United States Court of Appeals
For the First Circuit

No. 08-1056

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

BLUE CROSS BLUE SHIELD OF MASSACHUSETTS, et al.,

Plaintiffs, Appellees,

v.

ASTRAZENECA PHARMACEUTICALS LP,

Defendant, Appellant.

APPEAL FROM THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Patti B. Saris, U.S. District Judge]

Before

Howard, Circuit Judge,
Zobel[*] and Lisi,[**] District Judges.

Mark E. Haddad, with whom Nitin Reddy, Carter G. Phillips, Sidley Austin LLP, D. Scott Wise, Michael S. Flynn, Kimberley D. Harris, Davis Polk & Wardwell, Donald R. Ware, Sarah Cooleybeck and Foley Hoag LLP, were on brief for appellant.

Steve W. Berman, with whom Sean R. Matt, Hagens Berman Sobol Shapiro LLP, Jeffrey Kodroff, John A. Macoretta, Spector, Roseman

[*]Of the district of Massachusetts, sitting by designation.

[**]Of the District of Rhode Island, sitting by designation.

& Kodroff, P.C., Marc H. Edelson, Hoffman & Edelson, Thomas M. Sobol, Edward Notargiacomo, Hagens Berman Sobol Shapiro LLP, Kenneth A. Wexler, Jennifer Fountain Connolly and Wexler Toriseva Wallace LLP, were on brief for appellants.

Gregory G. Katsas, Assistant Attorney General, Michael J. Sullivan, United States Attorney, Michael S. Raab and Eric Fleisig-Greene, Attorneys, Appellate Staff, Civil Division, United States Department of Justice, on brief for amicus curiae United States in partial support of appellees and in partial support of affirmance.

September 23, 2009

HOWARD, Circuit Judge. AstraZeneca Pharmaceuticals LP ("AstraZeneca") appeals from the judgment of the district court, entered after a lengthy bench trial, of liability for unfair and deceptive business practices in violation of Massachusetts General Laws Chapter 93A ("Chapter 93A"). In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007). The district court found that AstraZeneca had caused the publication of false and inflated average wholesale prices ("AWPs"), a price used as a benchmark for various reimbursement plans, for its physician-administered drug Zoladex (goserelin acetate), thereby creating a windfall for the appellant's physician customers and causing injury to the government, insurers, and patients who were forced to pay inflated prices. AstraZeneca now brings a panoply of challenges to the district court's reasoning and result. Discerning no material factual or legal infirmity in the district court's disposition of the case, we affirm.

I. BACKGROUND

A. The Plaintiffs' Claims

This appeal arises out of a nationwide, multi-district class action involving the pricing of physician-administered drugs that were reimbursed by Medicare, private insurers, and patients' coinsurance payments. The challenged drug prices were those based

on AWP from 1991 through 2003.[1] The plaintiffs alleged in the district court that certain pharmaceutical companies, including AstraZeneca, violated Massachusetts' consumer protection statute by reporting AWPs that did not reflect the physicians' actual acquisition cost, or anything close to it, and thereby led the plaintiffs to overpay.

The core of the plaintiffs' claim is that the published AWPs for the drugs at issue did not reflect the discounts and rebates that the drug manufacturers offered to physician providers. Because AWPs were published in commercial publications (Red Book, Medispan, and First DataBank) and used as the predominant benchmark for calculating reimbursement, insurance, and coinsurance payments, the class plaintiffs alleged that inflating AWPs over the actual acquisition cost created a "spread" between the benchmark for the providers' reimbursement and the actual acquisition costs that the providers incurred.[2] This allowed the providers to buy the drug at a secret, lower price while being reimbursed for it at a public,

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[1]While the plaintiffs relevant to this appeal originally complained of conduct dating as far back as 1991, the district court found that the statute of limitations barred all claims before December 1997. In re Pharm., 491 F. Supp. 2d at 31-32. That ruling is not challenged in this appeal.

[2]Claims against Medispan and First DataBank, which are not part of this appeal, are fully described elsewhere. See Nat'l Ass'n of Chain Drug Stores v. New England Health Benefits Fund, Nos. 09-1577, 1578, 1579, 1580, ___ F.3d ___, 2009 WL 2824867 (1st Cir. Sept. 3, 2009); New England Carpenters Health Benefits Fund v. First DataBank, Inc., 244 F.R.D. 79 (D. Mass. 2007).

higher price, thereby creating a windfall each time a provider administered one of the drugs at issue. The plaintiffs further alleged that the defendant pharmaceutical companies then "marketed the spread" -- that is, advertised the potential windfall to providers -- in an attempt to increase the market share of their drugs over the competition. Motivating the plaintiffs' complaints, of course, is the fact that an increase to the AWPs directly resulted in an increase to the payments the plaintiffs were required to make in the form of reimbursement, insurance, or coinsurance. According to the district court's "representative" examples, markups to AWPs were significant and unpredictable, ranging from 27.0% to 1131.7%, depending on the drug and the year.

The plaintiffs' claims against AstraZeneca, discussed in detail below, relate to just one drug: Zoladex, an injectable, physician-administered drug that is primarily used to treat prostate cancer. Throughout the class period, Zoladex was a single-source drug -- that is, it did not face competition from a generic version of the same drug -- although it did face direct therapeutic competition from TAP Pharmaceuticals' product Lupron (leuprolide), which was also an injectable physician-administered drug.

B. Procedural History

The multidistrict litigation of which this case is a part is comprised of nearly one hundred cases involving AWP brought

against more than forty pharmaceutical defendants. The cases include the consumer and third-party payor class action lawsuit at issue here as well as lawsuits brought by several states, counties, and cities, and at least one qui tam lawsuit brought under the False Claims Act, 31 U.S.C. § 3729 et seq.

To manage this sprawling litigation, in March 2004 the district court structured the master consolidated class action into two separate tracks of defendants for purposes of class certification, summary judgment and trial. AstraZeneca was separated into "Track 1," the first of these groups to proceed through trial (and the only track at issue here). See In re Pharm. Industry Average Wholesale Price Litig., 230 F.R.D. 61, 65 n.1 (D. Mass. 2005).

In January 2006, the district court then certified three classes: (1) a nationwide class of Medicare beneficiaries who made co-payments for Medicare Part B drugs ("Class 1");[3] (2) a Massachusetts class of third-party payors that provided MediGap insurance which reimbursed Medicare beneficiaries for their co-payments for Medicare Part B drugs ("Class 2");[4] and (3) a

[3]The claims of Class 1 are not at issue in this appeal.

[4]"Class 2: Third-Party Payor MediGap Supplemental Insurance Class" is defined as:

> All Third-Party Payors who made reimbursements for drugs purchased in Massachusetts, or who made reimbursements for drugs and have their principal place of

Massachusetts class of customers and third-party payors that made payments based on AWP for (non-Medicare Part B) physician-administered drugs ("Class 3").[5] See In re Pharm. Indus. Average Wholesale Price Litig., 233 F.R.D. 229, 230-31 (D. Mass. 2006).

> business in Massachusetts, based on AWP for a Medicare Part B covered Subject Drug that was manufactured by AstraZeneca (AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P., and AstraZeneca U.S.) . . . .

In re Pharm. Indus. Average Wholesale Price Litig., 233 F.R.D. 229, 231 (D. Mass. 2006).

[5]"Class 3: Consumer and Third-Party Payor Class for Medicare Part B Drugs Outside of the Medicare Context" is defined as:

> All natural persons who made or who incurred an obligation enforceable at the time of judgment to make a payment for purchases in Massachusetts, all Third-Party Payors who made reimbursements based on contracts expressly using AWP as a pricing standard for purchases in Massachusetts, and all Third-Party Payors who made reimbursements based on contracts expressly using AWP as a pricing standard and have their principal place of business in Massachusetts, for a physician-administered Subject Drug that was manufactured by AstraZeneca (AstraZeneca, PLC, Zeneca, Inc., AstraZeneca Pharmaceuticals L.P., and AstraZeneca U.S.) . . . . Included within this Class are natural persons who paid coinsurance (i.e., co-payments proportional to the reimbursed amount) for a Subject Drug purchased in Massachusetts, where such coinsurance was based upon use of AWP as a pricing standard. Excluded from this Class are any payments or reimbursements for generic drugs that are based on [Maximum Allowable Cost] and not AWP.

In re Pharm., 233 F.R.D. at 231.

Prior to trial on the claims against the Track 1 defendants, the district court entertained cross-motions for summary judgment arguing the meaning of the term "average wholesale price" in the Medicare statute, 42 U.S.C. § 1395u(o) (1998). In November 2006, the district court construed the statutory term to mean "the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies," and including discounts and rebates. In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277, 278, 288 (D. Mass. 2006).

In June 2007, after a twenty-day bench trial including nearly forty witnesses and hundreds of documents and deposition transcripts, the district court issued a lengthy order finding AstraZeneca liable under Chapter 93A for the claims brought by the Class 2 and Class 3 plaintiffs. In re Pharm., 491 F. Supp. 2d at 31. The court found that:

> AstraZeneca acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for Zoladex which grossly exceeded actual physician acquisition costs by as much as 169% and then marketing these mega-spreads between the physician's acquisition costs and the AWP reimbursement benchmark in order to induce doctors to buy its drug based on the drug's profitability [rather than its therapeutic benefits]. The spread on Zoladex exceeded 100% from 1998 forward.

Id. The district court then awarded aggregate, class-wide damages to both Class 2 and Class 3. Id. In a later order, the district court found that AstraZeneca's conduct as to Class 2 was knowing

and willful, and awarded multiple damages; it declined, however, to make the same finding as to Class 3. In re Pharm. Indus. Average Wholesale Price Litigation, 520 F. Supp. 2d 267, 272, 273 (D. Mass. 2007).[6] The award against AstraZeneca (including prejudgment interest through August 1, 2007) reached nearly $13,000,000. AstraZeneca appeals.

II. STANDARDS OF REVIEW

"When a district court conducts a bench trial, its legal determinations engender de novo review." United States v. 15 Bosworth Street, 236 F.3d 50, 53 (1st Cir. 2001); see also Ahern v. Scholz, 85 F.3d 774, 798 (1st Cir. 1996). This includes questions of statutory interpretation, Gen. Motors Corp. v. Darling's, 444 F.3d 98, 107 (1st Cir. 2006), and determinations about the sufficiency of the evidence in a bench trial, 15 Bosworth Street, 236 F.3d at 53.

In contrast, findings of fact made after a bench trial are reviewed for clear error. Williams v. Poulos, 11 F.3d 271, 278 (1st Cir. 1993); Fed. R. Civ. P. 52(a)(6). "In other words, we

[6]While the district court was authorized to treble the damages as to Class 2 based on a finding that the conduct was knowing or willful, Mass. Gen. Laws ch. 93A, § 9(3A), it elected instead only to double the damages in recognition of the fact that "AstraZeneca was not the first to start the unlawful spread-marketing," and that AstraZeneca "tried to alleviate the impact of its conduct by providing free drugs to consumers, and initiating alternative methods for selling drugs . . . through a program [not pegged to AWP], which unfortunately turned out to be unsuccessful." In re Pharm., 520 F. Supp. 2d at 272.

will give such findings effect unless, after carefully reading the record and according due deference to the trial court's superior ability to judge credibility, we form a strong, unyielding belief that a mistake has been made." Williams, 11 F.3d at 278 (internal quotation marks omitted); see also 15 Bosworth Street, 236 F.3d at 53 ("This deference comports with common sense: a judge, sitting jury-waived, has the opportunity to see and hear the witnesses at first hand and to immerse himself in the nuances of the proof. Consequently, the appellate process ought to respect the trial judge's superior 'feel' for the case and his enhanced ability to weigh and evaluate conflicting evidence." (citing Anderson v. City of Bessemer City, 470 U.S. 564, 574-75 (1985))).

"A ruling that conduct violates Chapter 93A is a legal, not a factual, determination. Although whether a particular set of acts, in their factual setting, is unfair or deceptive is a question of fact, the boundaries of what may qualify for consideration as a Chapter 93A violation is a question of law." Incase Inc. v. Timex Corp., 488 F.3d 46, 56-57 (1st Cir. 2007) (internal quotation marks and citations omitted).

Other standards of review applicable to specific issues in AstraZeneca's appeal are set forth in the discussions that follow.

III. THE DISTRICT COURT'S DEFINITION OF "AVERAGE WHOLESALE PRICE"

AstraZeneca's initial challenge is to the district court's definition of "average wholesale price" as that term is used in the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (the "BBA"). According to AstraZeneca, the district court erred in concluding that the term should be interpreted in accordance with the alleged "plain meaning" of those words, which the district court determined to be the average of actual wholesale prices paid by providers, net of discounts and rebates. AstraZeneca argues that the plain meaning analysis was inappropriate because, inside the pharmaceutical industry, the term had long referred to the list prices in the industry publications -- such as Red Book, Medispan, and First DataBank -- and not actual transaction prices. Congress and the relevant regulators were aware of that industry usage and, AstraZeneca argues, they adopted it for purposes of the BBA; and AstraZeneca therefore should not be subject to liability for conduct consistent with the federal Medicare scheme. We disagree.

A. The History of "Average Wholesale Price" in the BBA

Congress created Medicare Part B in 1965 to establish a supplemental medical insurance program for senior and disabled citizens. See 42 U.S.C. §§ 1395j-1395w-4. The Secretary of the Department of Health and Human Services ("DHHS") oversees the program, and the Centers for Medicare and Medicaid Services

("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), administers it. See id. Among its services, Medicare Part B provides insurance for physician services, for which it has historically paid a "reasonable charge" limited to the lowest of the physician's actual charge, the physician's customary charge, or the prevailing charge in the relevant locality for similar services. See 42 U.S.C. §§ 1395*l*(a), 1395u(b); 42 C.F.R. §§ 405.500 et seq. For covered prescription or physician-administered drugs, Medicare Part B reimburses providers for up to eighty percent of the allowable cost, and the program's beneficiary pays the remaining twenty percent as a co-payment. See 42 U.S.C. § 1395*l*; Montana v. Abbot Labs., 266 F. Supp. 2d 250, 252 (D. Mass. 2003).

The term "average wholesale price" has not always featured in the Medicare Part B repayment lexicon. Prior to 1991, the standard for Medicare reimbursement was the "reasonable charge" of the covered services rendered. See 42 U.S.C. §§ 1395*l*, 1395u(o). In 1991, the Secretary of DHHS promulgated a new rule "set[ting] forth a fee schedule for payment for physicians' services" that incorporated the term "average wholesale price." Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 59,502, 59,502 (Nov. 25, 1991) (final rule). Notably, five months earlier, AWP was not part of the Secretary's proposed rule: although the Secretary believed that "ultimately there should be a

national fee schedule" for reimbursement, he concluded that "the large number of different drugs and the myriad . . . dosage levels" made such a schedule impractical. Medicare Program; Fee Schedule for Physicians' Services, 56 Fed. Reg. 25,792, 25,800 (June 5, 1991) (proposed rule). The Secretary's proposed rule therefore settled instead on continuing the "reasonable charge" regime that was already in place, proposing to reimburse at a rate of "85 percent of the national wholesale price." Id. The Secretary proposed that reimbursement level because "the Red Book and other wholesale price guides substantially overstate the true cost of the drugs" by failing to reflect "an average discount of 15.9 percent off the published wholesale price." Id. After receiving "a great many comments" on the proposed rule pointing out that, for providers, "many drugs could be purchased for considerably less than 85 percent of AWP . . . while others were not discounted," and that individual physicians often paid more for drugs than did pharmacies or large practices, the Secretary modified the proposed policy. 56 Fed. Reg. at 59,524-59,525. The final promulgated rule, effective January 1, 1992, stated:

> (b) Methodology. Payment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage.

> (c) Multiple-Source drugs. For multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

56 Fed. Reg. at 59,621 (promulgating 42 C.F.R. § 405.517 (1992)) (emphasis added). In promulgating the rule, the Secretary added that, to determine the estimated acquisition cost, "[c]arriers could survey a sample of the physicians who furnish the drugs to obtain cost information," or, "[a]s an alternative, carriers could request that physicians periodically provide cost information when they submit claims for payment for the drugs."[7] Id. at 59,525.

The reimbursement scheme was augmented again by the BBA, prompted in part by concerns that the "average wholesale price" was little more than a sticker price bearing little resemblance to the actual acquisition costs of the reimbursed drugs. For instance, the Senate Committee on Finance heard testimony from the Secretary of DHHS that "the AWP is not the average price actually charged by wholesalers to their customers . . . [r]ather, it is a 'sticker' price set by drug manufacturers and published in several commercial

[7]The United States, appearing as amicus curiae, notes that the part of this regulation requiring individual carriers to estimate the actual acquisition costs of covered drugs, and to base drug payments on the lower of the resulting estimate or the average wholesale price for each drug, was never implemented due to the Office of Management and Budget's concerns about the associated paperwork and reporting burdens.

catalogs." President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare: Hearing Before the S. Comm. on Finance, 105th Cong. 265 (1997) (statement of Donna E. Shalala, Secretary of Health and Human Services); see In re Pharm., 460 F. Supp. 2d at 280-81. Similarly, a report from the House of Representatives Committee on the Budget noted that "over the past several years," Medicare had been reimbursing certain drugs at rates far above providers' actual acquisition costs, sometimes nearly 1000 percent higher. H.R. Rep. No. 105-149, at § 10616 (1997); see In re Pharm., 460 F. Supp. 2d at 281. The committee therefore stated its intention that the Secretary of DHHS, "in determining the average wholesale price, should take into consideration commercially available information including such information as may be published or reported in various commercial reporting services." H.R. Rep. No. 105-149, at § 10616; see In re Pharm., 460 F. Supp. 2d at 281.

Based on these concerns, the BBA amended the relevant Medicare statute to state that "the amount payable for the drug or biological is equal to 95 percent of the average wholesale price." 42 U.S.C. §§ 1395u(o) (West 1998) (emphasis added). The BBA also directed the Secretary of DHHS to "study the effect on the average wholesale price of drugs and biologicals" of the statutory change,

and to report its findings to separate House and Senate committees. 42 U.S.C. § 4556(c) (West 1998).[8]

Roughly a year later, the DHHS regulations were amended to reflect the new statutory provision. See Medicare Program; Revisions to Payment Policies and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 1999, 63 Fed. Reg. 58,814, 58,905 (Nov. 2, 1998) (codified as 42 C.F.R. § 405.517 (1999)). In the process, HCFA noted that "the law does not define the term 'average wholesale price,'" but nonetheless interpreted the term for regulatory purposes to require that, "when there is an array of charges, the median is an appropriate measure of central tendency." Id. at 58,849.

As for the DHHS's study on the effect of the statutory change, the results were delivered to Congress in 1999. The Secretary included a history of Medicare drug reimbursement noting that "[f]or the past 13 years, the Office of Inspector General . . . has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs . . . it covers." It further noted that DHHS's attempt to fix the problem -- a proposal in the 1997 budget to base payment on the lower of the billed charge or the actual acquisition cost for the relevant drug

[8] The House of Representatives Committee on the Budget had also stated that it "will monitor AWPs to ensure that this provision does not simply result in a 5% increase in AWPs." H.R. Rep. No. 105-149, at § 10616; see In re Pharm., 460 F. Supp. 2d at 281.

-- had been "rejected in favor of the current rule, which is to pay based on the lower of the billed charge, or 95 percent of the AWP." Rep. to Cong., The Average Wholesale Price for Drugs Covered Under Medicare, DHHS 1-2 (1999); In re Pharm., 460 F. Supp. 2d at 281-82.

The BBA and the resulting regulations stayed in effect until 2003, when Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 ("2003 Act"), but the issue of Medicare reimbursement remained an active issue both in Congress and at DHHS throughout that time. In 2000, DHHS announced its intention to abandon AWP as a reimbursement baseline in favor of an alternative set of price lists, thereby provoking a letter from two Senators reminding the agency that "Congress [had] instructed [D]HHS to base Medicare reimbursement . . . on 95 percent of the 'average wholesale price,' or AWP, a term widely understood and indeed defined by [D]HHS manuals to reference amounts reflected in specified publications." See Letter from Sen. Christopher Bond and Sen. John Ashcroft to Donna E. Shalala, Secretary of Health and Human Services (Aug. 3, 2000); In re Pharm., 460 F. Supp. 2d at 282. Later that year, Congress passed an act requiring DHHS to study the difference between acquisition costs and AWP, and in the meantime, avoid actions that would "directly or indirectly decrease the rates of reimbursement . . . under the current medicare payment methodology . . . ." Medicare, Medicaid, and SCHIP Benefits

Improvement and Protection Act of 2000, Pub. L. 106-554, § 429(c), 114 Stat. 2763.

In 2001, while testifying before Congress about his concern that Medicare beneficiaries and taxpayers were paying "far more than the 'average' price that we believe the law intended them to pay," the Administrator of CMS stated, "The AWP is intended to represent the average price at which wholesalers sell drugs to their customers, which include physicians and pharmacies. . . . This Committee, CMS, the [DHHS] Inspector General (IG), and others have long recognized the shortcomings of AWP as a way for Medicare to reimburse for drugs." Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers: Joint Hearing Before the Subcommittee on Health and the Subcommittee on Oversight and Investigations of the House Commission on Energy and Commerce, 107th Cong. 87-88 (2001) (prepared statement of Thomas Scully, Administrator, CMS); see In re Pharm., 460 F. Supp. 2d at 282. This testimony prompted a question from the chairman of the committee that largely echoes the gravamen of the plaintiffs' complaint in this class action: "Why on earth do we have a system that requires a Medicare beneficiary to pay 20 percent as a copay of an artificial price?" Medicare Drug Reimbursements: A Broken System for Patients and Taxpayers, 107th Cong. at 95; In re Pharm., 460 F. Supp. 2d at 282.

Finally, in 2003, the DHHS Inspector General issued a "voluntary compliance" program for the health care industry that stated, "Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731-01, 23,733-27,734 (May 5, 2003).

The term "average wholesale price" was eventually phased out of the Medicare reimbursement scheme by the 2003 Act, which stipulated that reimbursements for drugs furnished on or after January 1, 2005 would be based on either a competitive acquisition program or an average sales price, a term defined to include all discounts and rebates. See 42 U.S.C. §§ 1395u(o), 1395w-3, 1395w-3a, 1395w-3b (2006). Although the 2003 Act retained the term "average wholesale price" in the interim, the House Committee on Ways and Means issued a report explaining its understanding of AWP in more detail, stating, "The term 'AWP' is not defined in statute or regulation, but generally, AWP is intended to represent the average price used by wholesalers to sell drugs to their customers." It continued:

> AWPs are not grounded in any real market transaction, and do not reflect the actual

> price paid by purchasers. Congress has long recognized AWP is a list price and not a measure of actual prices. Congress is now able to adopt an alternative basis for payment that will more accurately reflect actual acquisition costs for physicians. This will ensure that Medicare no longer bases its payments on prices that do not reflect prices otherwise available through market incentives and transactions.

H.R. Rep. No. 108-178, pt. 2, at 194, 197-98 (2003); In re Pharm., 460 F. Supp. 2d at 283.

B. The district court's decision of November 2, 2006

In arriving at its plain meaning interpretation of the term "average wholesale price," see In re Pharm., 460 F. Supp. 2d 277 (D. Mass. 2006), the district court first addressed the question of whether the term should be interpreted based on its plain meaning, or whether it is instead a term of art. See U.S. v. Lachman, 387 F.3d 42, 53 (1st Cir. 2004) ("[T]here are instances where a statutory or regulatory term is a technical term of art, defined more appropriately by reference to a particular industry usage than by the usual tools of statutory construction."). Noting that "a term must have an established and settled meaning to constitute a term of art," the district court canvassed the BBA's legislative history to conclude that "the weight of [this] history reflects congressional intent to have the AWP moored to actual wholesale pricing," not to the prices listed in the industry publications. In so doing, the district court emphasized Congress's various expressions of "consternation" over its

"awareness . . . that the pharmaceutical industry was overstating AWPs for some drugs in the industry publications," and that therefore "the AWP, as reported, was not a reasonable charge" for the relevant drugs. It also emphasized the committee report recommending that Congress order DHHS to take into account "commercially available information" including, but not limited to, published AWPs, and to monitor the effects of the new reimbursement standards to ensure that they were not circumvented by an offsetting increase in the published AWPs. The district court further concluded that, despite the existence of "some evidence" suggesting that the term "average wholesale price" may have had a settled meaning, "there is also evidence to the contrary," and therefore the defendants had not carried their burden to show that the term qualified as a term of art. The district court added that this conclusion was further merited given that the defendants' suggested meaning -- to quote the district court's paraphrase, "that AWP is a term of art for whatever benchmark was placed in industry publications" -- would lead to absurd results, among them, "DHHS and Congress would be surrendering all control over Medicare fiscal responsibility by anchoring Medicare reimbursement to a metric that is wholly dictated by the pharmaceutical industry."

The district court therefore proceeded with a plain meaning construction of "average wholesale price," citing dictionary definitions to arrive at its conclusion that the term

"include[s] discounts and rebates." In so doing, the district court relied heavily on what it inferred to be the policy behind the 1991 reimbursement regulations directing Medicare to reimburse the lower of the "estimated acquisition cost," based on surveys of actual acquisition prices, or the "national average wholesale price." That policy, the district court concluded, was "that the government gets the benefit of rebates and discounts" by paying the lower of those two rates. Finally, the district court noted that, by 2003, the term "average wholesale price" had become a term of art, finding that by that point "Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace."

C. Legal Standards

We review a district court's statutory construction de novo. Me. People's Alliance & Natural Res. Def. Council v. Mallinckrodt, Inc. 471 F.3d 277, 286-87 (1st Cir. 2006); Gen. Motors Corp., 444 F.3d at 107. "The Supreme Court has repeatedly emphasized the importance of the plain meaning rule, stating that if the language of a statute or regulation has a plain and ordinary meaning, courts need look no further and should apply the regulation as it is written." Textron, Inc. v. Comm'r, 336 F.3d 26, 31 (1st Cir. 2003). This is not to say, of course, that we always defer to plain language, but the circumstances under which we look behind plain language are extremely limited, usually

confined to those "rare cases [in which] the literal application of a statute will produce a result demonstrably at odds with the intentions of the drafters, and those intentions must be controlling" Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 571 (1982), or where the plain meaning will result in an absurd outcome, Textron, 336 F.3d at 31 (citing Sullivan v. CIA, 992 F.2d 1249, 1252 (1st Cir. 1993)). Additionally, "where a statutory or regulatory term is a technical term of art, defined more appropriately by reference to a particular industry usage than by the usual tools of statutory construction," we will employ that industry usage. Lachman, 387 F.3d at 53. But "this canon of construction requires the disputed term to actually be a technical term of art." Id. Finally, where a statute is ambiguous, we turn to the legislative history to determine Congress's intent. Gen. Motors Corp., 444 F.3d at 108.

D. Discussion

AstraZeneca argues that the district court made two significant errors. First, it asserts that the district court erred in holding that "average wholesale price" lacked an established and settled meaning and was not a term of art. According to AstraZeneca, the legislative history and legal context of the term clearly shows an established meaning: it referred to the prices published in the industry publications, which were known to exclude discounts. Whatever uncertainty there may have been

about the term's meaning, the argument continues, was not enough to justify the district court's conclusion that AWP was not a term of art. Second, AstraZeneca argues that the district court's "plain meaning" construction failed to account for the BBA's statutory context and history. Once the district court concluded that there was no settled meaning of the term "average wholesale price," its recourse should have been to the statute's legislative history and context, not to an alleged "plain meaning," particularly where that meaning is contrary to congressional intent.

For support, AstraZeneca focuses on four aspects of the BBA's legislative history and legal context. First, it notes that when HCFA first adopted the term "AWP" in its 1991 regulations, that phrase already existed in the industry publications, where it was used to describe list prices that did not reflect discounts available in the marketplace. It further notes that during the rulemaking process, HCFA explicitly referenced the published AWPs, and even advised Medicare carriers to obtain payment information from those industry publications.

Second, and taking issue with the district court's conclusion to the contrary, AstraZeneca argues that Congress was referring to the AWPs in industry publications when it passed the BBA in 1997. AstraZeneca relies on the reference to the AWPs "reported by the manufacturer[s]" contained in the congressional report accompanying the BBA. See H.R. Rep. No. 105-149, at 1398.

It also relies on DHHS's failed effort during the 1997 budget process to change the basis for payment from AWP to providers' acquisition cost, which was rejected by Congress in favor of the approach adopted in the BBA. See Rep. to Cong., The Average Wholesale Price for Drugs Covered Under Medicare, DHHS 1-2 (1999); In re Pharm., 460 F. Supp. 2d at 281-82.

Third, AstraZeneca argues that the district court's ruling conflicts with HCFA's own interpretation of the BBA as expressed, for example, in regulations directing that payment would be based on 95% of the national AWP as reflected in sources such as the industry publications even though those amounts were typically higher than the actual acquisition costs.

Fourth, AstraZeneca argues that the district court's definition of AWP is inconsistent with subsequent congressional actions demonstrating that Congress understood and intended that the statutory AWP standard was a reference to the industry publications, not to an average of actual transaction costs. Specifically, AstraZeneca points to the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, which provided for "additional payments" to some providers above the fee schedule amounts set by HCFA, see Pub. L. No. 106-113, 113 Stat. 1501, the refusal in 2000 to institute a new, alternative price list that reflected discounts, and the passage of the 2003 Act, which again used the term AWP, and which was issued with the Inspector

General's report acknowledging that AWP is not a measure of actual prices and does not reflect the discounts that manufacturers and wholesalers customarily offer to providers.

We find these arguments unpersuasive. As an initial matter, it is a stretch to point to this legislative history and statutory context for the proposition that AWP was a term of art in the BBA referring to the prices appearing in the industry publications. The letter from two Senators discussed above notwithstanding, Congress at no point adopted such a definition explicitly. On the contrary, both the DHHS regulation promulgated in 1991, which we assume Congress was aware of in 1997, and the BBA itself referred to the "average wholesale price" without reference to the industry publications.

Moreover, if the history discussed above demonstrates anything, it is that the precise meaning of "average wholesale price" was unsettled. In 1991, DHHS was concerned enough about the elastic definition of the term to specify an alternative metric -- estimated acquisition cost -- against which carriers were required to double-check claims based on AWP, a clear effort to ensure that Medicare and its beneficiaries would not be overcharged. When Congress reviewed this scheme in 1997, committees of both the Senate and the House heard testimony expressing concern over the possibility that AWP was merely a sticker price. This testimony appears to have struck home with at least the House committee,

which in expressing its intent to instruct DHHS to study the divergence between AWP and actual acquisition costs, suggested that DHHS "take into consideration" the industry publications. Were the prices reported in the industry publications themselves the very definition of AWP, as AstraZeneca suggests, then such an instruction would not only be unnecessary, it would be inscrutable. Finally, in interpreting the BBA and promulgating related regulations, none of the regulatory agencies explicitly adopted the purported technical meaning of AWP advanced by AstraZeneca. On the contrary, in 1998, HCFA noted that "the law does not define the term," and it directed that the proper definition when there is "an array of charges" should be the "median" charge, not whatever charge is listed in the industry publications. Similarly, in 1999, DHHS described its reimbursement approach as paying "based on the lower of the billed charge, or 95 percent of AWP" without any reference to the publications. And in 2001, the Administrator of CMS testified that AWP is the "average price at which wholesalers sell drugs to their customers," not the price as listed in the industry publications. Given these statements expressing uncertainty as to the meaning of AWP, and given the trial testimony, discussed in detail below, showing that the Class 2 and Class 3 plaintiffs were unaware of the size and extent of the spreads created by AWP inflation, AstraZeneca's contention that the BBA incorporated a technical term of art is not persuasive. See

Lachman, 387 F.3d at 53. The district court thus did not err in refusing to treat the term AWP in the BBA as a term of art.[9]

AstraZeneca's claim that the district court's construction failed to take into account the history and context of the BBA is also unpersuasive. This is not to say that AstraZeneca's arguments about congressional intent entirely lack force. On the contrary, AstraZeneca paints a fair picture of Congress and DHHS attempting to grasp and respond to the complicated billing practices of the pharmaceutical industry, and the conclusion AstraZeneca draws -- that Congress and DHHS intentionally adopted a definition of AWP about which they had concerns -- is enticing. But in drawing this conclusion, AstraZeneca has significantly understated Congress's unwavering commitment to the overarching policy that Medicare reimbursement should be reasonable and reflective of acquisition costs. This policy is evident in the "reasonable charge" regime explicitly in place prior to 1991, and contained in DHHS's proposed rule in 1991. It can be inferred from the final 1991 rule, which fleshed out what a "reasonable charge" is by directing reimbursement based on the

[9]We also share the district court's concern that Congress "could not have intended AWP to be a term of art for whatever price the industry chose to put in the industry publications," for that would "give the pharmaceutical industry free reign over drug pricing," and permit the industry to post AWPs "without any connection to prices in the market." This "absurd outcome" provides an additional, independent reason to reject AstraZeneca's purported technical definition. See Textron, 336 F.3d at 31.

lower of the national average wholesale price or the estimated acquisition cost, and which encouraged carriers to gather actual transaction data from physicians to ensure that these reimbursement bases reflected actual acquisition costs. The policy can also be seen in the repeated efforts during the late 1990's by DHHS to solve the problem of AWP becoming a sticker price subject to manipulation, and in Congress's repeatedly-demonstrated concern over this problem, as evidenced by its instructions, given on multiple occasions, for DHHS to monitor the apparent divergence of the AWP from acquisition costs. It is true, of course, that on some occasions during the relevant period, Congress appears to have been more reluctant than DHHS to abolish the role of AWP as a basis for Medicare reimbursement, and it is also true that various members of Congress at times expressed their views that the term AWP referred specifically to the prices reported in the industry publications. But for each of these historical details there exists a counterpoint in the record: an act of Congress demonstrating reluctance about the continued use of AWP, or another member of Congress expressing an opposing view.

On balance, we read the legislative history and statutory context to be one of slow adaptation to shadowy industry practices, not ratification of them. Congress's awareness of and response to the divergence of AWP from actual acquisition costs during the 1990's was an evolving one: the concerns expressed in 1991 and

studied in the late 1990's were finally addressed in 2003 (with solutions implemented in 2005). But throughout this period, there existed an unwavering commitment to the idea that Medicare and its beneficiaries should not be subject to overpayments, including those caused by prices reported in industry publications that failed to reflect acquisition costs. The legislative history and statutory context simply do not support the proposition that Congress was supportive of, or even acquiescent in, a scheme whereby the AWP represented a sticker price bearing no relation to actual acquisition costs, thereby leaving Medicare and its beneficiaries to pay vast multiples above what physicians paid for the drugs in question.[10]

[10]In its amicus brief, the United States argues that "[t]he phrase 'average wholesale price' . . . does not grant the pharmaceutical industry unfettered discretion to report drug prices that bear no relation to products' actual prices." The government takes the position that, "[s]ince its inception, Medicare Part B reimbursement has been based on the principle that providers may recover only a reasonable charge for their services or drugs. The introduction of average wholesale price into the Medicare lexicon . . . did not alter this basic tenet of the program. . . . [B]oth the text of the statute and the regulation on which it was based show a clear intent that average wholesale price, like any other metric for reimbursement under Medicare, reflect the actual price of the product that program beneficiaries receive." In response to AstraZeneca's argument that Congress had acquiesced in the practice of creating mega-spreads, the government notes that "[t]he notion that Congress intended to grant manufacturers unfettered discretion to adopt spreads exceeding 150%, and cabin the problem by reducing reimbursement rates by five percent [when it passed the BBA], is difficult to fathom," and observes, "[t]hat . . . opportunities for abuse exist in the Medicare statute does not mean that Congress has authorized them." We agree.

Finally, we note that we need not decide whether the district court's ultimate "plain meaning" analysis of "average wholesale price" was correct, for the district court did not rely on this specific definition as a trigger for liability under Chapter 93A. As explained in detail below, it rooted its ultimate liability finding not in the fact that spreads violated the "plain meaning" of "average wholesale price," but instead in the fact that, inter alia, the spreads exceeded industry expectations. See In re Pharm., 491 F. Supp. 2d at 32; see also id. at 97 ("What Congress understood and intended AWP to mean is not the same as what the industry understood. . . . Because information about the 20 to 25 percent spread was widespread in the industry, a violation of the Medicare statute by publishing an 'AWP' that was not a true average of wholesale prices does not trigger per se liability under Chapter 93A."). Nor has AstraZeneca argued that the BBA shielded the company's conduct from liability as an "exempted transaction" under Chapter 93A. See Mass. Gen. Laws ch. 93A, § 3 ("Nothing in this chapter shall apply to transactions or actions otherwise permitted under laws as administered by any regulatory board or officer acting under statutory authority of the commonwealth or of the United States. For the purpose of this section, the burden of proving exemptions from the provisions of this chapter shall be upon the person claiming the exemptions."). Thus, for purposes of this appeal, it is unnecessary to decide whether the term "average

wholesale price" admits of no spreads at all, as the district court appears to have concluded in its November 2006 order, or whether instead it admits of modest spreads (such as those created by prompt-pay discounts or formulaic markups from other published prices): whatever the correct interpretation of "average wholesale price" in the BBA, it in no way countenanced spreads in excess of the industry expectations discussed below. The relevance of the district court's interpretive order to this appeal is therefore not its precise definition of the term "average wholesale price," but instead its rejection of AstraZeneca's position that, under the BBA, that term referred to prices published in the industry publications which were known to exclude substantial discounts -- a rejection with which we entirely agree.

IV. PREEMPTION

AstraZeneca next argues that the district court's finding of liability under state law conflicts with and is preempted by federal law, and is thus invalid under the Supremacy Clause of the United States Constitution. U.S. Const. art VI, cl. 2. AstraZeneca has identified four different bases for this argument, but the thrust of each argument is the same: the choices made by Congress in enacting the complex set of Medicare statutes and in choosing the metrics by which Medicare Part B would compute and reimburse claims leave no room for additional state law regulation addressing the facts at issue here. For the reasons that follow,

we disagree, concluding instead that, in the circumstances of this case, Chapter 93A neither conflicts with nor is preempted by federal law.

A. The District Court's Ruling

In May 2003, the district court held that the appellees' claims under state consumer protection statutes are not preempted by federal law. In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 186-93 (D. Mass. 2003). Addressing the question of whether Congress had preempted state regulation by legislating in an area traditionally regulated by the states, the district court found "no evidence of a clear and manifest intent to preempt the entire field of state regulation of fraudulent medical billing practices" and "no legislative intent to preempt [state] supervision of the compensation of a person providing health services." It therefore held that "claims based on state consumer protection statutes that allege such practices are not preempted." Next, the district court held that the state law claims did not conflict with or stand as an obstacle to the Medicare program, finding that "[t]he maintenance of these consumer protection claims against the defendants will not actually conflict with the operation of the federal program," nor will they "require state courts to construe complex federal regulations," and opining that Supreme Court oversight of the state courts' application of federal law would suffice to ensure uniformity across jurisdictions.

Finally, addressing the question of whether allowing state court consumer protection actions, rather than insisting on administrative remedies, would conflict with CMS's responsibility to police fraud consistent with the Administration's judgment and objectives, the district court noted that "CMS does not make discretionary judgment[s] with respect to the statutorily defined Medicare Part B reimbursement rates, and does not approve the AWPs. Therefore, the decision of the pharmaceutical companies, not an agency action, is alleged to cause plaintiffs' harm," and "the Medicare statute does not preempt the state causes of action."

B. Legal Standards

"The ultimate determination whether federal law preempts [state law] presents a legal question subject to plenary review." Philip Morris Inc. v. Harshbarger, 122 F.3d 58, 62 (1st Cir. 1997) (citing United States v. R.I. Insurers' Insolvency Fund, 80 F.3d 616, 619 (1st Cir. 1996)).

"A fundamental principle of the Constitution is that Congress has the power to preempt state law." Crosby v. Nat'l Foreign Trade Council 530 U.S. 363, 372 (2000) (citing U.S. Const. art. VI, cl. 2; Gibbons v. Ogden, 9 Wheat. 1, 211 (1824); Savage v. Jones, 225 U.S. 501, 533 (1912); California v. ARC America Corp., 490 U.S. 93, 101 (1989)). It has long been the case that "[o]ur 'sole task' . . . is to determine the intent of Congress," Mass. Med. Soc'y v. Dukakis, 815 F.2d 790, 791 (1st Cir. 1987) (Breyer,

J.) (quoting Cal. Fed. Sav. & Loan Assoc. v. Guerra, 479 U.S. 272, 280 (1987)), and in so doing we have been mindful that "Congress does not cavalierly pre-empt state-law causes of action," Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996). Indeed, the Supreme Court recently reaffirmed these longstanding principles in Wyeth v. Levine, a case decided during the pendency of this appeal, when it described the "two cornerstones of our pre-emption jurisprudence":

> First, the purpose of Congress is the ultimate touchstone in every pre-emption case. Second, in all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.

129 S. Ct. 1187, 1194-95 (2009) (citations, quotation marks, and alterations omitted).

The clear and manifest purpose of Congress is most readily ascertainable when Congress includes an explicit preemption provision in an act. But such provisions are not required for a finding of preemption: implied federal preemption may be found where federal regulation of a field is pervasive, or where state regulation of the field would interfere with Congress's objectives. See Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 248 (1984); Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947). We have in the

past sketched numerous ways in which Congress may preempt state law:

> Congress might show that it intends to preempt state law by explicitly withdrawing the power of states to regulate within certain fields. Or, Congress might implicitly withdraw the states' power to regulate by creating a regulatory system so pervasive and complex that it leaves no room for the states to regulate. Congress might also enact a law such that compliance with both federal and state regulations is a physical impossibility, in which case the state statute must yield. Finally, . . . even in the absence of a direct conflict, a state law violates the supremacy clause when it stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Mass. Med. Soc'y, 815 F.2d at 791 (citations and quotation marks omitted). However Congress states or implies its intent to preempt, our preemption analysis invariably returns to those two cornerstones: Congress's purpose, and where it legislates in a field which the States have traditionally occupied, Congress's clear and manifest intent to preempt state law. Wyeth, 129 S. Ct. at 1194-95.

C. Discussion

AstraZeneca makes no argument that the application of Chapter 93A in this case has been explicitly preempted by Congress, or that compliance with both federal and state regulations is a physical impossibility. Instead, AstraZeneca argues that the federal Medicare statute leaves no room for state regulation, and alternatively, that Chapter 93A obstructs and undermines the

complex and carefully balanced federal Medicare reimbursement scheme. AstraZeneca makes these arguments in four forms, which we discuss in turn.

1. Congress's Careful Balancing of Policy Objectives

First, AstraZeneca argues that invoking state consumer protection laws to find liability for not reflecting discounts and rebates in the reported AWPs undermines Congress's decision to use the published AWPs as the basis for reimbursement under Medicare Part B. Such a finding of liability would, says the appellant, impose through state law what Congress itself rejected, namely, a cost-based reimbursement system.

This argument lacks merit for a number of reasons, not the least of which is the argument's reliance on the untenable interpretation of Congress's policy objectives discussed above. As we explained in the previous section, the legislative history and statutory context surrounding the Medicare program and the BBA does not support the assertion that Congress approved a reimbursement system by which pharmaceutical companies could be reimbursed at any rate they saw fit to have published as the AWP in industry publications, while simultaneously offering substantial discounts and rebates in the marketplace. On the contrary, throughout the time periods relevant to this appeal, Congress expressed its concern about Medicare overpayment when confronted with indications of such a practice, and it ordered studies of, and ultimately

retreated from, the use of AWP as a reimbursement benchmark. A state consumer protection law that covers as severe a form of price manipulation as this cannot be said to be contrary to Congress's intent in establishing and administering the Medicare program. This is especially so given that, as explained below, Chapter 93A was relied upon to check only the most pronounced cases of AWP inflation -- spreads that exceeded 30% -- and therefore were not used to impose the cost-based reimbursement system that AstraZeneca decries.

Moreover, it is telling that Congress did not go so far as to enact an express preemption provision at any time during the more than forty-year history of Medicare. See Wyeth, 129 S. Ct. at 1200 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the [Food, Drug, and Cosmetic Act's] 70-year history."). On the contrary, there can be no question that Congress was aware of the existence of state law liability schemes so ubiquitous as common law fraud and consumer protection statutes. See Penn. Med. Soc'y v. Marconis, 942 F.2d 842, 850 (3d Cir. 1991) ("[W]hen Congress remains silent regarding the preemptive effect of its legislation on state laws it knows to be in existence at the time of such legislation's passing, Congress has failed to evince the requisite clear and manifest purpose to supersede those state laws." (citing Cal. Fed. Sav. & Loan Assoc., 479 U.S. at 287-88)).

In fact, far from demonstrating Congress's intent to preempt state law consumer protection statutes, the Medicare statute reserves a regulatory role to the states that arguably includes some of the compensation aspects of this appeal, and in any event demonstrates Congress's intent to minimize federal intrusion into the area of provider compensation. See 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the . . . compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person."); see also Mass. Med. Soc'y, 815 F.2d at 791 (describing § 1395 as "explicitly stating the . . . intent to minimize federal intrusion" into the related "field of fee regulation of medical services for the elderly").

If anything, we are inclined to conclude that the opposite proposition is true: that Congress relied on the existence of state consumer protection and fraud statutes to combat severely manipulative pricing schemes resulting in overpayments by Medicare and its beneficiaries. At the least, this conclusion is implied by the fact that, for all of the Medicare statute's anti-fraud provisions, and despite Congress's and HCFA's ongoing concern

about the practice, the text of the Medicare statute does not provide an express remedy for practices like AWP inflation. It therefore appears that the state law cause of action at issue aids federal law rather than hinders it. But we need not go so far as to draw this conclusion; that Congress did not express or imply its intent to preempt state law is enough to defeat AstraZeneca's argument.

2. Exhaustion of Administrative Remedies

Second, AstraZeneca argues that the Chapter 93A claims of the Class 2 plaintiffs conflict with the mandatory administrative remedies specified in the Medicare statute for plaintiffs wishing to challenge Medicare determinations as to the approval and proper amount of Part B drug reimbursements.[11] AstraZeneca interprets the mandatory nature of these administrative remedies as evidence of a federal policy that federal determinations may not be called into question in any other forum. By turning to state law, AstraZeneca argues, the Class 2 plaintiffs have done just that.

This argument misstates the issue. Rather than challenging the approval and proper amount of Medicare Part B drug

[11]AstraZeneca makes this argument through reference to the appellate brief of Bristol-Myers Squibb Company, the Defendant-Appellant in the related case of In re Pharmaceutical Industry Average Wholesale Price Litigation, No. 08-1055 (1st Cir., filed Jan. 10, 2008). See Fed. R. App. P. 28(i). After hearing consolidated oral arguments in both cases, consideration of 08-1055 was stayed pending settlement negotiations, and it remains stayed today.

reimbursements, as AstraZeneca characterizes it, the Class 2 plaintiffs challenge the practice of publishing inflated AWPs. This is how the district court described the claims, In re Pharm., 491 F. Supp. 2d at 29, and given that the Class 2 plaintiffs do not challenge any aspect of the Medicare statute, its related regulations, or the specific agency decisions made pursuant to those laws, we think it is the better description.[12]

It is true, of course, that the chain of events by which the Class 2 plaintiffs suffered damages ran through the Medicare program, but that fact alone does not establish that the Medicare program is itself the basis of the lawsuit for purposes of determining whether the Class 2 plaintiffs were required to exhaust administrative remedies. See, e.g., Gully v. First Nat'l Bank, 299 U.S. 109, 115 (1936) ("Not every question of federal law emerging in a suit is proof that a federal law is the basis of the suit."). No such requirement applied in this case challenging AstraZeneca's business practices as unfair and deceptive under state law.

3. HCFA's Authority to Police Fraud

Third, and relying on Buckman Company v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001), AstraZeneca argues that the

[12]42 U.S.C. § 405(h) is not to the contrary. That section states in relevant part that "[n]o action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h). The Class 2 plaintiffs' action names none of these entities.

Class 2 plaintiffs' state law claims fail because they conflict with the Medicare statute, which empowers HCFA with broad authority to investigate and punish Medicare fraud.[13] HCFA's jurisdiction to police fraud itself must be protected, the argument runs, because only that agency can properly balance the need for enforcement with the need to protect difficult and often competing policy objectives, including adequately compensating physicians for Part B drugs and their administration, as well as guarding against excessive Medicare payments.

There is nothing inherently objectionable about the premise that a federal agency like HCFA is better positioned than a private plaintiff to balance the competing policy objectives of the program it administers, or the premise that, at times, the agency should take the laboring oar in combating fraud. But Buckman is not so broad as to sanction the conclusion that, simply because the deceptive practices at issue in this case depended on the structure of the Medicare program, it was therefore HCFA's exclusive dominion to combat them. On the contrary, Buckman addressed a more narrow scenario: the plaintiffs in that case employed a "fraud-on-the-agency" theory to attempt to create derivative standing for their own suits, which were based in state

[13]This argument, too, is made through reference to the appellate brief of Bristol-Myers Squibb Company, the Defendant-Appellant in the related case of In re Pharmaceutical Industry Average Wholesale Price Litigation, No. 08-1055 (1st Cir., filed Jan. 10, 2008).

law but which sought remedies for fraudulent misrepresentations made to the Food and Drug Administration ("FDA") during the approval process for certain medical devices. 531 U.S. at 343, 348. In finding implied preemption, the Buckman court emphasized that, "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in question[] [relating to various information that must be submitted to obtain the FDA's approval for a medical device]. On the contrary, the existence of . . . federal enactments is a critical element in their case." Id. at 353. It also emphasized its concern that "disclosures to the FDA, although deemed appropriate by the Administration, [would] later be judged insufficient in state court," thereby creating "an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA[]." Id. at 351.

In comparison, this case involves neither misrepresentations made directly to HCFA nor any concerns similar to the administrative efficiency concerns noted by the Buckman court. Perhaps more conclusively, unlike Buckman, this case cannot be said to involve disclosures that are fairly understood as to have been "deemed appropriate by the Administration." At issue here is a state law remedy for deceptive practices by a manufacturer against its customers. It is certainly true that the

deception touched on a federal agency, but policing deceptive conduct is nonetheless a traditional area of state concern giving rise to a remedial scheme that is separate and distinct from, and predates, the federal law in question.[14] At most, the state consumer protection laws at issue here operate in tandem with the anti-fraud provisions of the Medicare statute, but this alone is not enough to require a finding of implied preemption. See Buckman, 531 U.S. at 352-53 (citing Medtronic, 518 U.S. at 481).

4. Field Preemption

Fourth and finally, AstraZeneca argues that the federal Medicare scheme so completely occupies the field of Medicare payment determinations as to preclude supplemental state regulation of the amount that Medicare should pay on Part B drug claims.[15] According to AstraZeneca, the district court made two errors. First, it erred by misidentifying the "field" at issue as medical fee regulation or state regulation of fraudulent medical billing practices, rather than as the proper determination of the amount of

[14]We note that the regulation of medicine and its associated costs also "seems by tradition to be one of state concern." Mass. Med. Soc'y, 815 F.2d at 791. We also note that this court rejected arguments that the Medicare statute is a "comprehensive scheme" meant to displace common law remedies for collecting overpayments in United States v. Lahey Clinic Hosp., Inc., 399 F3d. 1, 17 (1st Cir. 2005).

[15]Again, AstraZeneca makes this argument through reference to the appellate brief of Bristol-Myers Squibb Company, the Defendant-Appellant in the related case of In re Pharmaceutical Industry Average Wholesale Price Litigation, No. 08-1055 (1st Cir., filed Jan. 10, 2008).

Medicare claims. AstraZeneca maintains that because states have no traditional state regulatory presence in that latter area, and because the federal interest in the field is significant and exclusive, the Class 2 plaintiffs' state law claims challenging the amount paid on Medicare claims are preempted. Second, and relatedly, AstraZeneca argues that the district court wrongly employed a presumption against preemption despite the history of federal regulatory presence in the area of Medicare payment determinations.

As already explained above, however, we disagree with AstraZeneca's characterization of the plaintiffs' claims: fairly interpreted, those claims do not challenge the approval or proper amount of Part B drug reimbursements, but rather the practice of publishing inflated AWPs; the claims are targeted at the conduct of pharmaceutical manufacturers, not the government; and the plaintiffs' complaints sound not in federal law, but in state consumer protection law. As such, the district court's characterization of the "field" is decidedly more appropriate to the inquiry than AstraZeneca's proposals, both of which inaccurately construe the plaintiffs' claims as claims against Medicare. With the claims properly described, it is obvious that states do in fact have a traditional regulatory presence in the field, and the federal interest, while arguably significant, is not exclusive. Finally, the mere presence of a federal interest does

not preclude the application of the presumption against preemption. As the Supreme Court recently clarified, the presumption against preemption applies in any field in which there is a history of state law regulation, even if there is also a history of federal regulation. Wyeth, 129 S. Ct. at 1195 n.3 ("The presumption . . . accounts for the historic presence of state law but does not rely on the absence of federal regulation.").

V. THE DISTRICT COURT'S "SPEED LIMIT"

AstraZeneca next takes aim at the district court's approach to finding liability under Chapter 93A, by which the court defined the spread between the published AWP and the actual acquisition costs that the government and the industry expected, and then used that expectation to define a limit to the spread for a particular drug in a particular year, beyond which liability for unfair and deceptive business practices would attach.[16] This limit was referred to as the "speed limit" and, alternatively, the "expectations yardstick"; spreads that exceeded the speed limit were referred to as "mega-spreads."

A. Dr. Hartman's Approach

In developing this approach and setting the speed limit, the district court relied heavily on the submissions of the

[16]Specifically, the district court held that exceeding the defined limit was unfair and deceptive until 2001, but only unfair thereafter, since "the cat was out of the bag, and the mega-spreads [had become] widely known." In re Pharm., 491 F. Supp. 2d at 95.

plaintiffs' expert, Dr. Raymond S. Hartman, a healthcare economist specializing in microeconomics and econometrics, with a focus on healthcare economics. Dr. Hartman's testimony concluded that the difference between the published AWP and the provider's acquisition cost for Zoladex (and other drugs) exceeded the expectations of Class 3 plaintiffs. To reach that conclusion, Dr. Hartman began with the analytic assumptions that the Class 3 plaintiffs were aware of some amount of discounting from the published AWP by drug manufacturers in their pricing to providers (i.e., a spread between the published AWP and the actual acquisition cost), and that because of this awareness, the third-party payors reimbursed for drugs at a rate some percentage lower than AWP.

According to Dr. Hartman, however, calibrating the proper reduction to AWP was tricky: the third-party payors would want to allow physicians to "cover their costs and perhaps earn a 'reasonable margin,'" but not allow them to reap an "'egregious profit.'" He noted, however, that because it was practically impossible for the Class 3 plaintiffs to determine the actual amount of AWP inflation -- the cost of gathering this data was "prohibitive" -- third-party payors were forced to estimate what discount to apply to the AWPs for purposes of reimbursement. These estimates, Dr. Hartman continued,

> would be the rule of thumb that [TPPs] would use when bargaining with providers. If manufacturers then secretly increased spreads such that reimbursement rates negotiated by

> TPPs with the expectation of [allowing for a reasonable margin] led in reality to "egregious" overcharges and profits unbeknownst to TPPs, . . . it would seem that those secret spreads constitute fraud injuring the Class members.

Dr. Hartman therefore testified that the key to defining a liability trigger in this case was to understand whether the Class 3 plaintiffs expected spreads as large as those at issue in this case, or whether those spreads so far exceeded TPP expectations as to constitute fraud.

To determine the Class 3 plaintiffs' expectations of the average spread between AWP and acquisition cost, Dr. Hartman used three different approaches. First, he examined the actual pricing history of a sample of single-source drugs that did not face competition. This inquiry was focused on understanding what spread was necessary to ensure that the providers would earn a reasonable profit when market-share considerations, and therefore AWP inflation, were not at issue. He found that this baseline spread was somewhere between 18%-27%, depending on the publication source for the AWP, and he thus chose 30% as his baseline spread "[t]o be conservative."[17] Therefore, Dr. Hartman concluded, spreads exceeding that baseline of 30% -- whether because of a raised AWP, a lowered actual acquisition cost due to rebates or discounts, or

[17]As the district court pointed out, Dr. Hartman's "spread" is calculated as a discount off of the average sales price, not off of the AWP; other publications refer to the "spread" as a discount off of AWP. See In re Pharm., 491 F. Supp. 2d at 87 n.61.

both -- indicated that the manufacturer had increased the spread on the drug in question beyond the amount necessary to ensure a reasonable margin for providers, presumably to manipulate market share. Dr. Hartman concluded that this 30% speed limit should trigger potential liability for fraud.[18]

Dr. Hartman's second method for determining the expectations of Class 3 plaintiffs was to review publically available government, academic, and popular studies of physician-assisted drugs concerning the relationship between AWP and actual acquisition cost for branded and generic physician-administered drugs. Dr. Hartman's review found that Class 3 plaintiffs reasonably anticipated spreads of 11% to 25%, well within his "conservative" 30% trigger for potential liability.

Finally, Dr. Hartman determined the expectations of Class 3 plaintiffs by examining the contracts between third-party payors and providers for evidence of what the parties expected the spread between AWP and actual acquisition cost to be. It was his position that the contract prices reflected information in the marketplace about provider costs. Dr. Hartman's review concluded that the reimbursement rates found in these contracts ranged from 16% below

[18]Notably, Dr. Harman's submissions assumed a 30% baseline spread for single-source drugs during periods where the drugs were without competition, and also for the six months after the first launch of a generic substitute. After six months of generic competition, he assumed that the competitive dynamics of the marketplace would control pricing.

to 15% above AWP, although the "better informed" third-party providers expected spreads on the order of a "20 to 25 percent markup above acquisition cost." Noting his belief that the results of his review of contracts were consistent with available literature and with Medicare reimbursement rates over the relevant time periods, Dr. Hartman concluded that the contracts showed that Class 3 plaintiffs generally believed that spreads ranged somewhere between 0% - 25%, which again fell well within his "conservative" 30% trigger for potential liability.

B. The District Court's Decision to Adopt Dr. Hartman's Approach

In ruling Dr. Hartman's submissions reliable and admissible under Federal Rules of Evidence 702 and adopting Dr. Hartman's approach to liability -- including his baseline 30% spread to trigger potential liability -- the district court addressed four chief objections to Dr. Hartman's submissions that were lodged by the defendants below, two of which merit discussion in the context of this appeal. See In re Pharm., 491 F. Supp. 2d at 89-93.

First, the district court rejected the defendants' position that payors' expectations about provider acquisition costs were unrelated to reimbursement rates. As evidence for this position, the defendants noted that payors did little to seek out actual cost data, chose not to negotiate reimbursement rates provider-by-provider, and failed to incorporate data about actual

acquisition costs into the reimbursement rate when that data was available. The defendants also criticized Dr. Hartman for failing to survey payors to determine their actual expectations about spreads and how those expectations factored into reimbursement rates. In rejecting this position, the district court cited to record evidence indicating the expense and difficulty of obtaining and using actual cost data on a provider-by-provider basis. The court noted testimony from third-party payors that expectations played an important part in setting reimbursement methodologies. And the court cited the "insurmountable barrier[s]" to shifting away from AWP-based reimbursement, which included the difficulty of creating an alternative system, and the potential that changes would create bad incentives for providers. The district court therefore concluded that "TPP knowledge about physician acquisition costs was material to the establishment of reimbursement rates."

Second, the district court rejected the defendants' position that 30% was an inappropriate figure to use as the outer limit of third-party payors' expectation about the size of AWP spreads. Instead, the defendants argued, expectations about spreads would not be so uniform: for example, payors would expect spreads to increase (and prices to drop) in response to competition, as competitors jockeyed for market share. In response, the district court noted simply that there was "no

evidence" that the TPPs had "any knowledge" of the "huge spreads . . . for the drugs on trial until the late 1990's."

Ultimately, the district court adopted Dr. Hartman's methodology and his 30% limit, specifically noting that it had taken into account the defendants' challenges to the accuracy of Dr. Hartman's data.[19]

C. AstraZeneca's Challenge

AstraZeneca makes only a passing challenge to the district court's decision to admit Dr. Hartman's expert testimony under Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993), and thus it has waived this objection on appeal. See United States v. Zannino, 895 F.2d 1, 17 (1st Cir. 1990) ("[I]ssues adverted to in a perfunctory manor, unaccompanied by some effort at developed argumentation, are deemed waived."). Instead, AstraZeneca focuses its objections on the district court's decision to credit Dr. Hartman's testimony, and on the legal propriety of the district court's decision to adopt the 30% "speed limit" as a trigger for potential liability.

"The finder of fact's determinations of credibility, and of the weight of the evidence in general, are not disturbed on appeal except for clear error." Mitchell v. United States, 141

[19]The district court applied the 30% limit to both Class 2 and Class 3, rejecting the plaintiffs' position that, as to Class 2, any spread between AWP and actual acquisition costs was per se unlawful. See In re Pharm., 491 F. Supp. 2d at 97.

F.3d 8, 17 (1st Cir. 1998). To find a clear error, we must be left with "the definite and firm conviction that a mistake has been made." Id. (citing Anderson, 470 U.S. at 573). In the context of an expert's testimony that has been credited by the trier of fact, finding clear error requires that we find the testimony "inherently implausible, internally inconsistent, or critically impeached." Id. (citing Keller v. United States, 38 F.3d 16, 25 (1st Cir. 1994)).

Hoping to demonstrate the district court's clear error in adopting Dr. Hartman's methodology and his 30% speed limit, AstraZeneca attacks the evidentiary basis for Dr. Hartman's conclusions and points up a number of alleged methodological flaws. It first argues that Dr. Hartman's conclusions were implausible. It points to "extensive evidence" from TPP witnesses suggesting that the TPPs viewed AWP as having no predictable relationship to acquisition costs, and that some TPP witnesses were aware of spreads exceeding 30%. It further argues that some TPP's had themselves purchased drugs from manufacturers at discounted prices, and it asserts that Dr. Hartman "did not account for the actual knowledge and expectations of class members." Dr. Hartman's evidence, AstraZeneca concludes, is therefore inadequate to support the district court's decision to credit his submissions and adopt his methodology and 30% potential liability trigger.

The testimony that AstraZeneca relies on suggests that some third-party payors may have doubted the wisdom of pegging reimbursement rates to AWP, or that some may have known of instances of significant spreads, but it is not one-sided enough to call the district court's weighing of the evidence into question under the clear error standard of review that we must apply. Mitchell, 141 F.3d at 17. As an initial matter, some of the testimony cited by AstraZeneca to demonstrate TPP knowledge of increased spreads is contradicted by the testimony of other representatives from the same organization, and occasionally by other portions of testimony from the same representative. For instance, whereas AstraZeneca correctly notes that John Killion of Blue Cross Blue Shield of Massachusetts ("BCBS-MA") referred to AWP as an "artificial price," the appellant omits the fact that this comment was made in a speculative manner ("I think there were discussions internally within the company in regards to AWP and people referring to AWP as . . . an artificial price") and with regard to another TPP, Tufts Health Plan, not BCBS-MA. Nor does AstraZeneca mention that Mr. Killion also stated that he did not understand how AWP was calculated or how it related to the actual prices that were paid by physicians for physician-administered drugs. Other witnesses from BCBS-MA who were more familiar with physician-administered drugs testified to their belief that AWP was an actual average, or at least an accurate pricing signal. And

while BCBS-MA may have purchased some drugs at steeply discounted prices, these purchases were made through subsidiaries that were sold in 1997, just two years after BCBS-MA instituted AWP-based pricing. In re Pharm., 491 F. Supp. 2d at 48. Moreover, in those two years, the subsidiaries did not share detailed pricing information for their purchases with their parent. Id. Additionally, the record contains ample evidence, some of which is recited in the district court's opinion, that third-party payors depended on the AWP as a reliable indicator of actual acquisition costs. See In re Pharm., 491 F. Supp. 2d at 135-36. Finally, testimony at trial from the fund administrator at plaintiff Pipefitters Local 537 ("Pipefitters") demonstrated that Pipefitters believed AWP to be an actual average of prices, and testimony from Plaintiff Sheet Metal Workers National Health Fund's third-party administrator, Southern Benefits Administrators, Inc., indicated that the administrator itself shared that belief. Thus, we cannot say that the record evidence is inconsistent with the district court's decision to credit Dr. Hartman's submissions. See Fed. Refinance Co., Inc. v. Klock, 352 F.3d 16, 29 (1st Cir. 2003) (noting that a trial court, sitting as factfinder, is "free to choose between the two versions of the truth and draw appropriate inferences" (citing Anderson, 470 U.S. at 574; Keyes v. Sec'y of the Navy, 853 F.2d 1016, 1020 (1st Cir. 1988))).

Nor are we persuaded by AstraZeneca's argument that Dr. Hartman's methodology inadequately accounted for the effects of generic competition, which AstraZeneca argues would, as a matter of common sense, lead industry participants to expect a larger spread. Far from abandoning common sense, Dr. Hartman's methodology was grounded in it: he began with the fair assumption, consistent with the record evidence, that third-party payors expected a spread large enough to ensure a "reasonable margin" for providers, but not so large as to allow them to earn "egregious profits." This assumption is beyond cavil. Then, to determine where that line was likely to have been drawn, he focused on breakthrough innovator drugs, which because they were "uniquely efficacious," did not depend on deep provider margins to maintain their market share. See Home Placement Serv., Inc. v. Providence Journal Co., 819 F.2d 1199, 1205-06 (1st Cir. 1987) (noting, in the antitrust context, that the proper approach to measure damages is "with reference to the performance of . . . closely comparable firms in the same industry that, unburdened by the proscribed anticompetitive activity, successfully managed to earn profits"). His study indicated that 30% provided a "conservative" estimate of the expected spread for those drugs. Of course, the introduction of generic competition undoubtedly introduces new market share considerations, creating incentives for manufacturers to inflate AWPs to deepen provider margins for their drugs. But the existence

of these incentives does not prove that third-party payors acquiesced in, or expected the manufacturers' creation of, mega-spreads leading to egregious provider profits. The contrary suggestion strike us as being akin to arguing that, because car owners and mechanics have strong incentives to overstate the costs of repairs and then share in insurers' overpayments, the insurers who overpay have acquiesced in the scheme or should expect to be defrauded on a widespread basis. And even if third-party payors might have had reason to expect increased spreads when generic competition entered the market, significant portions of the record evidence demonstrate that TPPs in fact believed AWP to be reflective of acquisition costs. On balance, any infirmities in Dr. Hartman's handling of generic competition were insufficient to render clearly erroneous the district court's decision to credit his analysis. See Mitchell, 141 F.3d at 17.

AstraZeneca's attempt to demonstrate the internal inconsistency of Dr. Hartman's submissions is no more successful. To support the claim, AstraZeneca argues that Dr. Hartman's use of the "revealed preferences method," which looked to the contracts between TPPs and providers for evidence of TPPs' expectations regarding acquisition costs, was inconsistent with both the "extensive evidence" at trial showing that TPPs knowingly permitted doctors to earn a profit on the drugs at issue, and with Dr. Hartman's own data showing that some TPPs were willing to pay

fifteen percent above AWP. As noted by the district court, the defendants below did "not challenge[] the revealed preferences method as unreliable," In re Pharm., 491 F. Supp. 2d at 88, and consequently this argument is waived on appeal. Campos-Orrego v. Rivera, 175 F.3d 89, 95 (1st Cir. 1999) ("We have reiterated, with a regularity bordering on the echolalic, that a party's failure to advance an issue in the nisi prius court ordinarily bars consideration of that issue on appellate review.").

In any event, as to the matter of the evidence showing that TPPs permitted some spread, it is enough to say that the issue at trial was not the existence of a spread, but the extent of it, and that the evidence presented generally supported Dr. Hartman's identification of a 30% speed limit as a conservative estimate of the outer limit of TPPs' expectations. And as to the matter of Dr. Hartman's own data showing that TPPs occasionally paid 15% above AWP, it is significant that Dr. Hartman specifically considered this data in his report and found that the above-AWP payments were typically made by less-informed TPPs who believed that AWP was an actual average, whereas the "better informed" TPPs expected spreads on the order of 20-25%, or in other words, within the 30% speed limit. See In re Pharm., 491 F. Supp. 2d at 88 & n.64. We see nothing "so internally inconsistent or implausible on its face" about these findings that a "reasonable factfinder would not credit

it," see Anderson, 470 U.S. at 575, and therefore we discern no clear error warranting reversal.[20]

Finally, we reject AstraZeneca's argument that the district court's decision to adopt a 30% trigger for potential liability was inconsistent with its own ruling that there was no basis for imposing per se liability under Chapter 93A, and therefore constituted an error of law. On the contrary, the 30% trigger represents not a per se threshold for liability based on the violation of a separate legal duty, but instead, as is clear from the intensely factual nature of Dr. Hartman's report and the district court's June 2007 order, constitutes a specific factual conclusion about what conduct in this case would trigger potential liability under Chapter 93A as to these plaintiffs based on the TPPs' actual commercial expectations.

In short, Dr. Hartman's testimony was admissible and the district court was entitled to rely on it: it was plainly plausible and internally consistent, and it was not critically impeached. See Mitchell,141 F.3d at 17. It was also consistent with testimony suggesting that TPPs and their administrators were

[20]AstraZeneca's challenge to Dr. Hartman's own documentary evidence, which contained passing references to mega-spreads dating back as far as 1992, also fails. Dr. Hartman was not engaged in an inquiry into the size of actual spreads, but instead into payors' understanding of the size of those spreads. That there were some observations in the public literature referring to mega-spreads during the relevant time period does not alone suffice to put the lie to the payors' testimony at trial, or to demonstrate a serious internal inconsistency in Dr. Hartman's submissions.

unaware of the extent of mega-spreads and, on occasion, even believed AWP to be an actual average of prices. See id.; Fed. Refinance Co., Inc., 352 F.3d at 29. We therefore conclude that the evidence before the district court was sufficient to permit the court to adopt Dr. Hartman's finding that the outer limit of TPPs' expectations for a reasonable spread was 30%, and consequently for the court to use that figure as a trigger for potential liability under Chapter 93A.

VI. THE MERITS

AstraZeneca also challenges the district court's merits analysis under Chapter 93A. For the reasons that follow, those challenges are unpersuasive.

A. Legal Standards

A ruling on what conduct violates Massachusetts' consumer protection statute, Chapter 93A, is a legal determination, reviewable under a de novo standard. Incase Inc., 488 F.3d at 56. However, the question of "whether a particular set of acts, in their factual setting, is unfair or deceptive is a question of fact," id. at 57 (quotation omitted), and we will only disturb the district court's findings of fact if they are clearly erroneous, Williams, 11 F.3d at 278. A factual finding is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." Anderson, 470 U.S.

at 573; see also Dedham Water Co., Inc. v. Cumberland Farms Dairy, Inc., 972 F.2d 453, 457 (1st Cir. 1992) (requiring the reviewing court to have "a strong, unyielding belief that a mistake has been made" before setting aside a factual finding). Mixed questions of fact and law are also subject to the "clearly erroneous" standard, unless the district court's findings are premised on a mistaken view of the applicable law, in which case our review is de novo. Juno SRL v. S/V Endeavour, 58 F.3d 1, 4 (1st Cir. 1995).

Chapter 93A, prohibits "unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, §2. It provides for a private cause of action to any "person" who, inter alia, "has been injured by another person's use or employment of any method, act or practice declared to be unlawful by section two," id. § 9, or "[a]ny person who engages in the conduct of any trade or commerce" who, inter alia, "suffers any loss of money or property, real or personal, as a result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two," id. § 11. "To prove such a claim, it is neither necessary nor sufficient that a particular act or practice violate common or statutory law." Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc., 552 F.3d 47, 69 (1st Cir. 2009) (citing Kattar v. Demoulas, 739 N.E.2d 246, 257 (Mass. 2000)). Instead, Massachusetts courts "evaluate unfair

and deceptive trade practice claims based on the circumstances of each case," leaving "the determination of what constitutes an unfair trade practice to the finder of fact." Id.

That is not to say, of course, that the factfinder is entirely unguided when assessing whether conduct is unfair or deceptive. An act or practice is "unfair" if it is "within at least the penumbra of some common-law, statutory or other established concept of unfairness," is "immoral, unethical, oppressive, or unscrupulous," and "causes substantial injury to consumers (or competitors or other businessmen)." Id. (quoting Mass. Eye & Ear Infirmary v. QLT Phototherapeutics, Inc., 412 F.3d 215, 243 (1st Cir. 2005)); see also PMP Assocs., Inc. v. Globe Newspaper Co., 321 N.E.2d 915, 917 (Mass. 1975). The "crucial factors" in an unfairness inquiry are "the nature of [the] challenged conduct and on the purpose and effect of that conduct." Mass. Employers Ins. Exch. v. Propac-Mass, Inc., 648 N.E.2d 435, 438 (Mass. 1995) (citing PMP Assocs., Inc., 321 N.E.2d 915).

An act or practice is "deceptive" if it has the "capacity or tendency" to deceive. Abruzzi Foods, Inc. v. Pasta & Cheese, Inc., 986 F.2d 605, 605 (1st Cir. 1993). The plaintiff need not necessarily prove actual reliance on a misrepresentation; rather, the plaintiff must prove "a causal connection between the deception and the loss and that the loss was foreseeable as a result of the deception." Int'l Fid. Ins. Co. v. Wilson, 443 N.E.2d 1308, 1314

(Mass. 1983); see also Fraser Eng'g Co., Inc. v. Desmond, 524 N.E.2d 110, 113 (Mass. App. Ct. 1988) ("Nor is proof of actual reliance on a misrepresentation required so long as the evidence warrants a finding of a causal relationship between the misrepresentation and the injury to the plaintiff.").

It should also be noted that Chapter 93A does not attach liability for all of the unseemly business practices justly loathed by consumers and business professionals. Instead, at least between commercial entities, "the objectionable conduct must attain a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce," Mass. School of Law at Andover, Inc. v. American Bar Ass'n, 142 F.3d 26, 41-42 (1st Cir. 1998) (quoting Levings v. Forbes & Wallace, Inc., 396 N.E.2d 149, 153 (Mass. App. Ct. 1979)); that is to say, "the defendant's conduct must be not only wrong, but also egregiously wrong," id. at 41.

Finally, while adherence to industry standard or custom is one factor that can support a finding of no liability under Chapter 93A, see, e.g., James L. Miniter Ins. Agency, Inc. v. Ohio Indem. Co., 112 F.3d 1240, 1251 (1st Cir. 1997), the existence of an industry-wide practice does not itself constitute a complete defense to a Chapter 93A claim, see Commonwealth v. DeCotis, 316 N.E.2d 748, 753 (Mass. 1974).

B. The District Court's Findings

1. The District Court's Approach to Liability

In its order applying these standards to the evidence adduced at trial, the district court identified three "salient factors" on which it focused its inquiry into whether the conduct complained of was unfair or deceptive. In re Pharm., 491 F. Supp. 2d at 101-02.

First, the district court inquired into whether the spreads for Zoladex exceeded 30%.[21] In assessing this factor, which the district court described as "the most important inquiry" for purposes of finding liability, the court focused on the "extent and duration of the spreads" to assess whether they were "egregious."

Second, the district court looked to AstraZeneca's "history of creating the spread." To do so, the court inquired whether the appellant took an active hand in increasing the AWP, as opposed to increasing the spread solely by offering discounts and rebates. The district court interpreted increases to the AWP as evidence of unethical conduct because raising the AWP imposed costs on the payors and patients but not on the pharmaceutical manufacturer. The district court also examined the "legitimacy of the list price from which the markup is derived," attempting to distinguish between list prices at which substantial sales were

[21]As explained above, 30% represented the court's "conservative" estimate of the outer limit of payors' expectations for spreads during the relevant time period.

made, and those that were created only to increase the AWP. And the district court interpreted evidence of AWP increases made in response to Congress's change in reimbursement rates as evidence of unethical conduct.

Third, the district court looked to evidence of "proactive scheme[s] to market the spread to doctors by encouraging them to purchase drugs because of their profitability [to the providers] rather than their therapeutic qualities," citing OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731-01, 23,737 (May 5, 2003), for examples of these schemes including "sales representatives promoting the spread as a reason to purchase the product."

After rehearsing these three factors, the district court specifically noted that the liability inquiry would nonetheless depend on the "particular circumstances of each manufacturer and each drug for each year," and that "no single factor is necessarily determinative."

Specific challenges to the district court's approach will be addressed below; suffice it to say here that this framework fits comfortably within the legal requirement to "evaluate unfair and deceptive trade practice claims based on the circumstances of each case." Mass. Eye & Ear Infirmary, 552 F.3d at 69 (citing Kattar,739 N.E.2d at 257).

2. The District Court's Fact Findings

The district court made a series of fact findings as to AstraZeneca. See In re Pharm., 491 F. Supp. 2d at 50-54. It noted that AstraZeneca was the manufacturer of Zoladex, and that at all relevant times, Zoladex was a single-source drug, although it competed directly with TAP Pharmaceuticals' Lupron.

The district court further found that, throughout the class period, AstraZeneca provided a suggested AWP for Zoladex to industry publications (First DataBank and Red Book). The court found that although the industry publications actually published the AWP, it was AstraZeneca that effectively controlled the published price. AstraZeneca also provided the "Wholesale Acquisition Cost" ("WAC") for Zoladex, which was another list price for Zoladex (and, during the class period, also not reflective of actual aquisition costs, see id. at 40, 52, 53); the AWP for Zoladex remained a constant 25% above the WAC.

According to the district court, AstraZeneca's pricing strategy for Zoladex was largely driven by its competition with Lupron, and therefore both the AWP and the WAC for Zoladex remained lower than the corresponding prices for Lupron. The average annual price increases also stayed low, averaging just 2.6%, and for some time the price increases even stayed below the rate of inflation. This pricing strategy seemed viable, but it nonetheless backfired because the AWP-based reimbursement system created financial

incentives for physicians to choose higher priced products for Medicare customers. Therefore, from 1990 to 1993, when AstraZeneca sold Zoladex at WAC (minus a 2% prompt pay discount) and kept the corresponding AWP beneath that of Lupron, Zoladex was unable to increase its market share vis-à-vis Lupron as providers sought to reap the spread on Lupron, which was also 25% at the time, but which because of Lupron's higher price resulted in more income for providers.

By 1995, AstraZeneca decided to change the focus of its pricing strategy away from being the low-cost drug, and instead focus on creating the largest possible "total return to practice." The mechanism for doing so, according to a "pricing strategy" memo quoted by the district court, was to "widen[] the margin between the published price and the acquisition cost . . . through several pricing manipulations: 1) Increase the AWP[,] 2) Decrease the acquisition cost relative to the AWP, or 3) Both 1 and 2. . . . [I]t is recommended that we exercise option #3 . . . ." AstraZeneca thus began offering discounts to physicians while continuing to increase the WAC and AWP: in 1995, the spread between the AWP and the actual selling price for Zoladex exceeded 40%, and by 2002 it was more than 140%. During this time period, the district court found, AstraZeneca also began using this pricing scheme to market Zoladex to providers, using letters and sales calls designed to show the "return to practice," that is, the

profits providers could realize by taking advantage of Zoladex's inflated AWP under the AWP-based reimbursement system.

The district court explicitly found that AstraZeneca "knew that its AWP was a fictitious and artificial number . . . but felt no need to correct its reported price because it was standard industry practice to leave the AWP at 25 percent above WAC." It also believed that it was saving money for Medicare and its patients by creating incentives for providers to choose the lower-priced Zoladex over the higher-priced Lupron, leaving Alan Milbauer, AstraZeneca's Vice President of Public Affairs, to remark at trial, "I actually felt good about that."[22]

This is not to say that AstraZeneca was entirely unconcerned about risks associated with its spread marketing -- the district court noted, for example, internal memoranda discussed the "risk from a regulatory/legal/public relations perspective" and the possibility that "HCFA may see through this strategy" -- but the company deemed those risks "unlikely," and it believed that it could justify its pricing scheme to the public based on "1) increased manufacturing costs, 2) no increase in realized revenue per unit [to AstraZeneca] over the last two years, and 3) [a

[22]We note that AstraZeneca's choice to judge its conduct relative to that of TAP Pharmaceuticals was ill-considered, given that TAP Pharmaceuticals later pled guilty to conspiring to violate the Prescription Drug Marketing Act based on conduct during this time period that included, inter alia, inflating AWP to market the spread. See In re Pharm., 491 F. Supp. 2d at 52 n.34.

constant published] price . . . that is $112.50 less [than the corresponding price for Lupron]." AstraZeneca therefore continued to market the spread, lobbied against the 1998 Medicare legislation which reduced reimbursement from 100% of AWP to 95% of AWP, and when that legislation passed, it increased the price of Zoladex 6.9% to "compensate[] the customer [that is, the provider] for this 5% plus provide[] an additional improvement in return to practice."[23]

3. The District Court's Liability Findings

Analyzing these facts under the three-criteria approach to liability outlined above, the district court found that

> AstraZeneca acted unfairly and deceptively by causing the publication of false and inflated average wholesale prices for Zoladex which grossly exceeded actual physician acquisition costs by as much as 169% and then marketing these mega-spreads between the physician's acquisition costs and the AWP reimbursement benchmark in order to induce doctors to buy its drug based on the drug's profitability.

In re Pharm., 491 F. Supp. 2d at 31; see also id. at 102-03. Specifically, the district court found that the spreads for Zoladex exceeded the 30% speed limit every year from 1996 through 2002, showing that "the extent and duration of the [inflated] spreads were significant." It further found that from 1996 through 1999,

[23]The district court noted that AstraZeneca also set up alternative reimbursement programs that didn't rely on AWP and that therefore eliminated the providers' incentive to choose higher-priced drugs. These programs were ultimately unsuccessful and/or cancelled due to the company's fears of a backlash from providers.

AstraZeneca raised both the WAC and the corresponding AWP for Zoladex despite decreasing the actual sales price, thus ensuring that beneficiaries' and TPPs' costs increased even though providers' costs dropped. The district court noted that AstraZeneca raised the AWP to counteract Medicare's reduced reimbursement rate in 1998, and finally, it found that AstraZeneca's efforts to promote the "return to practice" available to providers who prescribed Zoladex constituted active marketing of the drug based on profitability rather than therapeutic benefits. For these reasons, the district court "easily" found that AstraZeneca's "actions were unfair to consumers and TPPs under Chapter 93A. Accordingly, [it found] liability for Zoladex during the years 1998-2002."

C. AstraZeneca's Challenges

AstraZeneca mounts three challenges to the district court's merits analysis, two of which we discussed extensively above and will therefore only touch upon again here.[24]

First, AstraZeneca argues that by 1997, TPPs "knew, or should have known, that AWP was a benchmark price that had no necessary relationship to actual average sales prices, net of discounts." This knowledge, AstraZeneca asserts, "defeats Plaintiffs' claims of deception." We discussed the TPPs' knowledge

[24]As noted above, AstraZeneca has not argued that its conduct was shielded from liability as an "exempted transaction" under Chapter 93A. See Mass. Gen. Laws ch. 93A, § 3.

of AWP inflation in detail when discussing AstraZeneca's preemption challenge, above, and need not repeat that discussion here. Suffice it to say that we are unpersuaded by the record evidence that the TPPs' knowledge of systematic AWP inflation was sufficient to insulate AstraZeneca from Chapter 93A liability for its practices of reporting one, inflated price for reimbursement purposes while charging another, discounted price to providers, and for using the difference between these prices as a lever for increasing the market share for Zoladex.

We also note that Tagliente v. Himmer, 949 F.2d 1 (1st Cir. 1991), the case relied upon by AstraZeneca for the proposition that a Chapter 93A plaintiff's knowledge of the extent of a potentially-deceptive business practice is immaterial if that plaintiff has any knowledge of the practice at all, cannot bear the weight of that proposition. In that case involving a misrepresentation relating to the presence of water and wetlands on a piece of property, we explicitly noted that the relevant facts "could have been easily verified." Id. at 7. In contrast, the district court in this case found that the costs of acquiring and acting upon the information necessary to understand the full extent of the AWP inflation were "prohibitive." In re Pharm., 491 F. Supp. 2d at 86.

Nor is Ahern v. Scholz, 85 F.3d 774 (1st Cir. 1996), contrary to the district court's liability finding. That case

involved a dispute over royalties earned by a songwriter; the songwriter claimed that certain deductions taken by his manager violated Chapter 93A. Id. at 778-79. In assessing the deductions under Chapter 93A, we found that although they were "commercially unreasonable," the manager's level of rascality was not sufficient to rise to the level of a violation of Chapter 93A. Id. at 799-800. Central to that holding was the fact that the producer "did not seek to conceal the nature of the deductions: he laid them out [in a written statement itemizing the royalties and deductions] in varying levels of detail." Id. at 799. AstraZeneca thus cites Ahern for the proposition that it should be released from liability under Chapter 93A because it "did not seek to conceal" the discounts available for Zoladex, but rather "reported them accurately to HCFA via Medicaid, and to TPPs through a program AstraZeneca designed to allow TPPs to benefit from them." This argument mirrors those made below in which AstraZeneca maintained that it had disclosed accurate pricing data by "report[ing] an accurate average manufacturer's price ('AMP'), a close proxy for [the providers' actual acquisition costs], to CMS for purposes of Medicaid," and that it had "discussed the spreads with TPPs" in the context of an alternative reimbursement system. In re Pharm., 491 F. Supp. 2d at 102-03. The district court, however, considered and rejected these arguments, finding that "AMP data is confidential information that is unavailable to TPPs or consumers." It also

rejected a similar argument relating to prices AstraZeneca provided to another private pharmaceutical data provider, IMS Health, finding that those prices "did not provide a clear representation of the spreads on Zoladex." The district court also noted that, even though "some data regarding the acquisition costs of Zoladex was leaking into the public domain, this did not mitigate the unfairness of using a grossly inflated AWP" because "TPPs faced significant structural impediments to changing the reimbursement system for a single drug," and "Medicare reimbursement was statutorily based on AWP, so TPPs were stuck paying for Zoladex based on the inflated AWP provided by AstraZeneca." We find no clear error in these findings of the district court, which are sufficient to undercut AstraZeneca's contention that it did not keep the spreads secret. Ahern is therefore distinguishable.

AstraZeneca's second, related argument challenging the district court's merits analysis is that the district court erred in finding that the government and TPPs were "locked" into AWP-based reimbursement and "could [not] move quickly or effectively to fix the problem." AstraZeneca argues that, even if true, this fact is not enough to show that the defendants "caused [the plaintiffs] to act differently from the way [they] otherwise would have acted," as required under Chapter 93A. Tagliente, 949 F.2d at 7 ("An act is 'deceptive' under chapter 93A 'if it could reasonably be found to have caused a person to act differently from the way he

otherwise would have acted.'" (quoting Lowell Gas Co. v. Attorney Gen., 385 N.E.2d 240, 249 (Mass. 1979); Purity Supreme, Inc. v. Attorney Gen., 407 N.E.2d 297 (Mass. 1980))). Moreover, AstraZeneca argues that even if the district court applied the correct legal analysis, its underlying fact finding was inaccurate because neither the government nor the TPPs were "at the mercy" of the defendants, as the district court suggested. A fair assessment of the knowledge and equities as to both parties, AstraZeneca argues, reveals that AstraZeneca misled and was unfair to nobody, and therefore should not be subject to liability under Chapter 93A.

We disagree that the district court erred at all, much less committed the clear error required to upset a factual finding, when it concluded that the TPPs were effectively locked into the AWP-based repayment system. Copious evidence before the district court documented the administrative difficulties of abandoning that payment system in favor of another, and even Dr. Gregory Bell, an expert who testified on behalf of the defendants below, acknowledged that competitive concerns impeded any single TPP's ability to migrate to new payment systems, testifying that "an individual payor on its own is in a very difficult position to do this." See In re Pharm., 491 F. Supp. 2d at 96 ("Even Dr. Bell admitted that TPPs faced several significant impediments to quickly changing reimbursement practices."). The district court was therefore supported by the record evidence when it concluded that

"neither the TPPs nor the government could move quickly or effectively to fix the problem." Moreover, the district court adopted the finding of Dr. Meredith Rosenthal, an expert offered by the plaintiffs, who testified that class members paid more for drugs based on a false AWP than they would have if the defendants had reported a true AWP. Id. These findings are more than adequate to justify the district court's conclusions that, under the circumstances of this case, "the fact that the TPPs have been slow to change their reimbursement systems does not negate causation," and that even after 2001, when the TPPs' knowledge about spreads was more comprehensive, "the [defendants'] conduct was still egregious under the unfairness prong of Chapter 93A." The TPPs were both unaware of the full extent of the AWP inflation and unable to adapt to it "quickly and effectively," as they undoubtedly would have liked to given that the inflation of AWPs caused them to pay more than they would have had the AWPs been accurately reported. That is sufficient under the circumstances to meet Chapter 93A's causation requirement. See Int'l Fid. Ins. Co., 443 N.E.2d at 1314 (requiring the plaintiff to show a "causal connection between the deception and the loss and that the loss was foreseeable as a result of the deception").

AstraZeneca's third argument challenging the district court's merits analysis is that the plaintiffs failed to prove actual damages, asserting that none of the named plaintiffs

presented "evidence of what they paid for Zoladex from 1997 through 2003," "formulas they used to determine physician reimbursements for Zoladex," "testimony as to their own individual expectations of the difference between Zoladex AWPs and average actual sales prices of Zoladex," or testimony as to "how such expectations altered the reimbursement formulas to which they agreed with treating physicians" or otherwise "had any impact on their determinations of appropriate and competitive reimbursement levels for physicians." AstraZeneca further argues that this failure defeats not only the plaintiffs' Chapter 93A claim, but their very standing under Article III to bring the lawsuit in the first instance. See SBT Holdings, LLC v. Town of Westminster, 547 F.3d 28, 37 (1st Cir. 2008) ("A plaintiff must have Article III standing. To proceed, he or she must 'adequately establish: (1) an injury in fact . . . ; (2) causation . . . ; and (3) redressability.'" (quoting Sprint Commc'ns Co. v. APCC Servs., Inc., 128 S. Ct. 2531, 2535 (2008)) (citation omitted)).

As described above, however, the evidence presented by Dr. Hartman and Dr. Rosenthal belies AstraZeneca's claims about insufficient evidence of damages. That evidence included, inter alia, testimony from TPPs as to their understanding of the AWP benchmark and its relationship to actual acquisition costs, TPP contracts, industry reports and public literature, and expert testimony at trial. Dr. Hartman's findings were based on a

methodology that the district court ruled was reliable and admissible, and resulted in calculations of the amount of actual, not speculative, damages incurred by the plaintiffs as a result of overpayments due to AstraZeneca's actions.[25] Dr. Rosenthal testified that had the AWPs not been inflated, the plaintiffs would not have paid as much as they did. And as the Supreme Court long ago recognized in the antitrust context, overpayment is a cognizable form of injury. See Reiter v. Sonotone Corp., 442 U.S. 330, 342 (1979).[26] We have been presented with no reason to deviate from that approach here.

For these reasons, we find AstraZeneca's challenges to the district court's merits analysis unpersuasive.

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[25]Additional challenges to the district court's damages rulings are discussed below.

[26]AstraZeneca further argues that its practice of inflating the AWP and marketing the spread to practitioners resulted in a net benefit to plaintiffs because Zoladex was at all times the lower-cost alternative to its competitor, Lupron. The district court dismissed this argument by concluding that "one fraud does not excuse another," In re Pharm., 491 F. Supp. 2d at 103, and we agree. AstraZeneca's better course would have been to blow the whistle on TAP's scheme; it should not now be relieved, in whole or in part, from the damages it caused simply because when it engaged in the same scheme, it may have left money on the table by pricing Zoladex lower than Lupron. As Dr. Hartman put it in his December 16, 2006 rebuttal testimony, "[I]t makes no economic sense when evaluating the consequences of fraud and abuse to characterize . . . the lesser harm perpetuated by one wrongdoer as a 'savings' [simply] because the victim would have suffered a greater harm by the other wrongdoer."

VII. CLASS-WIDE JUDGMENT

The final issue presented by this appeal is whether the district court erred in entering a class-wide judgment, a decision that AstraZeneca argues impermissibly abridged its substantive rights and violated due process by depriving AstraZeneca of its opportunity to raise individual defenses against each class member. See Amchem Prods. Co. v. Windsor, 521 U.S. 591, 612-13 (1997) (citing the Rules Enabling Act, 28 U.S.C. § 2072(b) for the proposition that Fed. R. Civ. P. 23 may not be used to "abridge, enlarge or modify any substantive right").

AstraZeneca mounts three specific challenges on this score: first, that the district court erred in extending its judgment under § 9 of Chapter 93A to TPPs whose proper avenue for relief was § 11, a section to which the plaintiffs allegedly did not prove themselves entitled; second, that the class-wide judgment denied the company its opportunity to litigate individualized issues of knowledge, causation, and injury as to absent class members; and third, that the district court's aggregate damages calculation overlooked the individualized circumstances of absent class members. We discuss each argument in turn, but we find none persuasive.

A. Section 9 vs. Section 11

AstraZeneca's first challenge to the class-wide judgment is its claim that the district court erred in allowing the TPPs to

advance their claims under § 9 rather than requiring them to make proof under § 11. As the district court properly noted, at least as to "business" claims, § 9 and § 11 of Chapter 93A are "mutually exclusive and plaintiffs' claims can proceed under only one section." See Mass. Gen. Laws ch. 93A, § 9 ("Any person, other than a person entitled to bring action under section eleven of this chapter . . . may bring an action . . . ." (emphasis added)); Cont'l Ins. Co. v. Bahnan, 216 F.3d 150, 156 (1st Cir. 2000) ("By their terms, however, [§ 9 and § 11] of chapter 93A . . . are mutually exclusive."); Frullo v. Landerberger, 814 N.E.2d 1105, 1112 (Mass. Ct. App. 2004) ("A business claim cannot be asserted under § 9."). Whereas "§ 9 affords a private remedy to the individual consumer who suffers a loss as a result of the use of an unfair or deceptive act or practice," § 11 grants a cause of action to "[a]ny person engaged in the conduct of any trade or commerce," which the Massachusetts Supreme Judicial Court ("SJC") has interpreted to mean persons "acting in a business context." Lantner v. Carson, 373 N.E.2d 973, 976 (Mass. 1978).[27]

Calling the distinction between § 9 and § 11 "as clear as mud," the district court cited Linkage Corporation v. Trustees of Boston University, 679 N.E.2d 191, 209 (Mass. 1997), for the

[27]The statutory definition of "person" includes "natural persons, corporations, trusts, partnerships, incorporated or unincorporated associations, and any other legal entity." Mass. Gen. Laws ch. 93a, §1(a).

proposition that "[i]n most circumstances, a charitable institution will not be engaged in trade or commerce when it undertakes activities in furtherance of its core mission," and distinguished that situation from one where a non-profit organization "is merely engaged in the customary business necessary to meet its charitable purpose," see Trs. of Boston Univ. v. ASM Commc'ns, Inc., 33 F. Supp. 2d 66, 77 (D. Mass. 1998). It then turned to the individualized circumstances of this case to guide its inquiry into whether the plaintiffs are entitled to sue under § 9, see Begelfer v. Najarian, 409 N.E.2d 167, 176 ("[B]usiness context must be determined from the circumstances of each case."), and specifically focused on the nature of the transaction, the character of the parties involved, and whether the transaction is motivated by business or personal reasons, see Linkage Corp., 679 N.E.2d at 207 (citing Begelfer, 409 N.E.2d at 191).

As to plaintiff BCBS-MA, the district court found that in its conduct relevant to its claims in this case, BCBS-MA was "a non-profit organization acting pursuant to its legislative mandate," engaged in "a key part of its core mission," and "not motivated by the desire to make money," and therefore is eligible to "bring [its] claims under § 9 of Chapter 93A." Without significant explanation, the district court extended this

conclusion, "[a] fortiori," to all "Taft-Hartley funds,"[28] and also to the other class-member TPPs. In a footnote, the district court added, "After reviewing the relevant law, plaintiffs also satisfy the requirements necessary to bring an action under § 11. Given the finding that § 9 is appropriate, I decline to fully address those issues."[29] In re Pharm., 491 F. Supp. 2d at 82 n.53.

On appeal, AstraZeneca trifurcates its challenge. It first argues that the named plaintiffs should not be allowed to avail themselves of § 9 because, although they are non-profit entities, each was acting in a business context and thus brings a business claim better suited for § 11. It next argues that, even if the named plaintiffs could proceed under § 9, the district court made no fact findings sufficient to extend the same conclusion to the for-profit TPP class members. Finally, AstraZeneca argues that the district court's alternative holding that "plaintiffs also satisfy the requirements necessary to bring an action under § 11" was both inadequately explained and wrong, and thus cannot render the errors as to § 9 harmless. We need not reach the first two of these challenges because we reject the third: even assuming,

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[28]"A Taft-Hartley fund provides health and welfare benefits for union members. The fund, pursuant to federal law, is 'administered jointly by employer-designated trustees and union-designated trustees.'" In re Pharm., 491 F. Supp. 2d at 49 n.29 (quoting Levy v. Local Union No. 810, 20 F.3d 516, 517-18 (2d Cir. 1994)).

[29]We note that the question of whether the TPPs met the requirements of § 11 was extensively briefed to the district court.

arguendo, that the district court erred in allowing the plaintiffs to proceed under § 9, we agree with the district court that the TPPs have satisfied the requirements necessary to bring an action under § 11.

With regard to § 11, AstraZeneca argues that the TPPs failed to establish "that its monetary loss arises from a business transaction between the plaintiff and defendant," stressing that the TPPs and AstraZeneca were not in privity with each other on any of the payments at issue. However, Massachusetts appellate courts have counseled that, in a fraud suit under § 11 where "the parties are engaged in more than a minor or insignificant business relationship," such privity is not required. Standard Register Co. v. Bolton-Emerson, Inc., 649 N.E.2d 791, 795 (Mass. App. Ct. 1995) ("[P]rivity is not required to maintain a nonwarranty-based action under 93A, i.e., one based on fraud, so long as the parties are engaged in more than a minor or insignificant business relationship." (citing Mongeau v. Boutelle, 407 N.E.2d 352 (Mass. App. Ct. 1980))).[30] What, specifically, constitutes a "minor or

[30]Szalla v. Locke, 657 N.E.2d 1267 (Mass. 1995), is not to the contrary. Szalla involved a claim under Chapter 93A that arose out of a failed business venture. Noting that "[i]t is well established that disputes between parties in the same venture do not fall within the scope of . . . § 11," and finding that "[t]he defendant was not purchasing the plaintiff's services," but rather "[t]he defendant and the plaintiff made a private arrangement to form a business together," the SJC held that "[t]he association between the plaintiff and the defendant . . . is not the kind of commercial transaction regulated by the statute." Id. at 1269-70.

insignificant business relationship" has not been fully fleshed out in the Massachusetts courts, but it has been described as requiring that "there must exist some commercial relationship between the parties or the plaintiffs must demonstrate that the defendants' actions interfered with trade or commerce." Spencer v. Doyle, 733 N.E.2d 1082, 1087 (2000). For purposes of our § 11 analysis, that the relationship between AstraZeneca and the TPPs meets the standard articulated in Spencer is obvious.

Additionally, Massachusetts case law offers ample support for allowing the plaintiffs to proceed under § 11 despite the lack of strict privity with AstraZeneca. For instance, in Standard Register, two defendants who "fraudulently negotiated and induced the . . . contract with Standard Register and orchestrated the misrepresentation regarding the progress of the project," but who were not in privity with the plaintiffs, were sued under § 11. 649 N.E.2d at 795. Similarly, in First Enterprises, Ltd. v. Cooper, 680 N.E.2d 1163 (Mass. 1997), the SJC discussed, with approval and in the context of a § 11 claim, a case in which a buyer of goods sued attorneys despite the fact that the attorneys were not party to the relevant transaction because the attorneys had "injected themselves" into the trade and commerce of the buyer and seller. Id. at 1165-66 (discussing Kirkland Constr. Co. v. James, 658 N.E.2d 699 (Mass. App. Ct. 1995), and concluding that the defendant in First Enterprises "did not, as did the attorneys in Kirkland,

supra, inject himself into trade or commerce" (internal quotation marks omitted)).

We see no meaningful distinction to be drawn between these cases and the case at bar. For years, AstraZeneca manipulated a pricing scheme by repeatedly making misrepresentations about the cost of Zoladex that it knew would increase the amount the plaintiffs would have to pay. That scheme exploited the TPPs, who believed the AWPs reflected actual acquisition costs, lacked information about the extent of the deceptive practices, were unable to adapt, and were among the obvious and foreseeable victims. AstraZeneca thus unquestionably orchestrated the scheme at the cost of the TPPs, and in so doing, effectively determined the amount of money the TPPs would overpay to their counterparties for Zoladex. That the fraud passed through third parties along the way does not reduce or undo the influence AstraZeneca wielded over the plaintiffs' transactions, an influence so great as to make AstraZeneca and the plaintiffs a kind of functional counterparties. See Leardi v. Brown, 474 N.E.2d 1094, 1101 (Mass. 1985) ("Technicalities are not to be read into the statute in such a way as to impede the accomplishments of substantial justice."); see also Ameripride Linen & Apparel Svcs., Inc. v. Eat Well, Inc., 836 N.E.2d 1116, 1122 (Mass. App. Ct. 2005) (same). Thus, and mindful of the duration and extent of the unfair and deceptive practices, the ongoing business relationship between

AstraZeneca and the TPPs cannot be said to be minor or insignificant.

AstraZeneca also argues that the plaintiffs may not avail themselves of § 11 because AstraZeneca's conduct did not occur "primarily and substantially within" Massachusetts. See Kuwaiti Danish Computer Co. v. Digital Equip. Corp., 781 N.E.2d 787, 797 (Mass. 2003) ("[A] a judge should . . . determine whether the center of gravity of the circumstances that give rise to the [§ 11] claim is primarily and substantially within the Commonwealth."). Whether this test has been met is a question of law subject to plenary review, id., but it is also a "fact intensive" inquiry that is "unique to each case," and "[s]ignificant factors . . . for one case may be nonexistent in another," id. at 798. In all events, however, the focus of the inquiry should be on "the purpose and scope" of Chapter 93A. Id. at 799.

Under these standards, we agree with the district court's finding that the plaintiffs may proceed under § 11. It is true, of course, that Delaware is AstraZeneca's principal place of business, that its conduct was directed nationwide, and that none of the pricing compendia at issue were located in Massachusetts. That does not mean, however, that AstraZeneca is correct to assert that its conduct "had no connection to Massachusetts," for it is clear from the district court's findings that AstraZeneca's conduct directly, and by design, affected physicians in Massachusetts and

caused financial injury to payors in Massachusetts. It is also true that the definitions of Class 2 and Class 3 are limited to plaintiffs with a substantial connection to Massachusetts. Moreover, the purpose of Chapter 93A to "encourage more equitable behavior in the marketplace and impose liability on persons seeking to profit from unfair practices" is undoubtedly consistent with allowing a § 11 claim under the circumstances. Arthur D. Little, Inc. v. Dooyang Corp., 147 F.3d 47, 55 (1st Cir. 1998) (quoting Linkage Corp., 679 N.E.2d at 208). Especially in light of the burden of proof on this issue, which rests with AstraZeneca, see Kuwaiti Danish Computer Co., 781 N.E.2d at 797 (citing Mass. Gen. Laws ch. 93A, § 11), we agree with the district court that the TPPs have satisfied this requirement of § 11.

Finally, AstraZeneca's complaint that the district court's explanation for its § 11 finding was inadequate is unavailing. The district court's finding as to § 11 is explicit, and even if it weren't, we are empowered to affirm the district court based on any grounds apparent in the record. See Pequero-Moronta v. Santiago, 464 F.3d 29, 34 (1st Cir. 2006); United States v. Podolsky, 158 F.3d 12, 16 (1st Cir. 1998) ("[A]n appellate court, faced with the task of reviewing an inscrutable order, may either remand for a fuller exposition or act, without remanding, if a reasonable basis supporting the order is made manifest on the record.").

We will therefore not disturb the district court's finding that the TPPs may avail themselves of § 11; the district court's errors regarding § 9, if any, were harmless.

B. Absent Class Members

The gravamen of AstraZeneca's second challenge to the class-wide judgment is its contention that the district court erred in addressing only the knowledge of the named class representatives, particularly BCBS-MA, when examining the TPPs' knowledge and expectations as to AWP inflation. Pointing to the "fact-specific" nature of the district court's analysis of the class representatives' knowledge and expectations, AstraZeneca argues that the district court should also have analyzed -- and permitted discovery and inquiry by AstraZeneca into -- the knowledge and expectations of absent class members, who AstraZeneca maintains may have had more knowledge than BCBS-MA did of Zoladex pricing. After all, the argument runs, even if BCBS-MA lacked sufficient knowledge of AWP inflation and Zoladex pricing,[31] there is reason to believe that other, absent class members could have had more refined knowledge and expectations than the class representatives did, for at least some of the absent class members were large and sophisticated TPPs who had been directly offered

[31]In the section of its brief attacking the class-wide judgment, AstraZeneca again assails the district court's findings as to BCBS-MA's knowledge and expectations regarding AWP inflation and Zoladex pricing. As we rejected those arguments above, we need not do so again here.

discounts on Zoladex by AstraZeneca through various cost-reduction programs. Thus, AstraZeneca argues that because the actual knowledge and expectations of the absent class members was never established, the district court "excused [them] from having to establish each element of their Chapter 93A claims," thereby "den[ying] AstraZeneca its right to defend itself."

This argument, of course, is a familiar one in the context of class action lawsuits. It is beyond question that, under some circumstances, constitutional principles prohibit a court from relying on proof relating to the class representatives to make class-wide findings. But it is equally obvious that class-action litigation often requires the district court to extrapolate from the class representatives to the entire class; for example, the district court employed just this kind of analysis without objection in this very case when it applied the "discovery rule" to determine when the statute of limitations should cut off the plaintiffs' claims, but did not make specific findings as to each class member, In re Pharm., 491 F. Supp. 2d at 75-80. See also Hansberry v. Lee, 311 U.S. 32, 42-43 (1940) ("It is familiar doctrine of the federal courts that members of a class not present as parties to the litigation may be bound by the judgment where they are in fact adequately represented by parties who are present, or where they actually participate in the conduct of the litigation in which members of the class are present as parties, or where the

interest of the members of the class, some of whom are present as parties, is joint, or where for any other reason the relationship between the parties present and those who are absent is such as legally to entitle the former to stand in judgment for the latter." (citations omitted)). The district court in this case determined that the class was adequately represented when it certified the class, and it carefully examined the representatives' knowledge and expectations as to spreads. As a general matter, this is precisely the kind of analysis that Rule 23 was designed to permit, and it would quickly undermine the class-action mechanism were we to find that a district court presiding over a class action lawsuit errs every time it allows for proof in the aggregate.

More specifically, the district court's aggregate determination as to knowledge and expectations was permissible and appropriate for two reasons. First, AstraZeneca and the other Track 1 defendants were allowed ample opportunity to depose TPPs prior to trial -- in all, these defendants deposed roughly fifty TPPs, and multiple representatives from many of those. Despite this extensive discovery, AstraZeneca marshals no specific evidence on appeal to suggest that absent class member TPPs had knowledge or expectations that differed substantially from class representative BCBS-MA.

Instead, AstraZeneca states, without record citation, that "many other payers" were as sophisticated as BCBS-MA, and that

unnamed TPPs who "fully understood that AWPs were not predictably related to acquisition costs or who understood the pricing of Zoladex itself were permitted to recover." Yet the portions of the record to which AstraZeneca cites to raise the specter of individualized differences in knowledge and expectations among the class members in fact demonstrate the class members' similarities, for the record citations contain evidence that the class-member TPPs were offered the same opportunities to take advantage of discounts and rebates that BCBS-MA was offered. If these portions of the record suggest anything, it is that, contrary to AstraZeneca's position, BCBS-MA was a good proxy for the class members' knowledge and expectations.[32]

Second, the district court's conclusions about industry knowledge and expectations were based on a careful analysis of the class representatives and on expert testimony that was properly admitted, and therefore it did not exhibit any of the evils paraded in AstraZeneca's brief with references to cases such as Broussard v. Meineke Discount Muffler Shops, Inc., 155 F.3d 331, 343 (4th

[32]Moreover, the testimony from the roughly fifty TPPs appears to have been enough to allow defendants' expert Dr. Eric M. Gaier to form opinions about aggregate TPP knowledge: under the subheading "TPPs are typically knowledgeable and sophisticated," he used observations about the largest TPPs, including BCBS-MA, to extrapolate imputed knowledge and expectations of smaller TPPs. That defendants' own expert managed to reach conclusions by the same method that AstraZeneca now claims was improper due to individualized circumstances must, as a matter of common sense, cast doubt on the plausibility of AstraZeneca's position.

Cir. 1998) (reliance on a fictitious, composite plaintiff "divorced from any actual proof of damages" whereas North Carolina law required "reasonable certainty" about lost profits awards), Western Electric Company v. Stern, 544 F.2d 1196 (3d Cir. 1976) (unduly limited discovery), and Cimino v. Raymark Inustries, Inc., 151 F.3d 297 (5th Cir. 1998) (extrapolating damages from personal injuries and death from a set of sample cases).

Nor are we persuaded that this case has individualized circumstances similar to those at issue in McLaughlin v. American Tobacco Co., 522 F.3d 215 (2d Cir. 2008), where the Second Circuit cast doubt on the use of common proof to establish reliance and causation among a class of smokers who had purchased "light" cigarettes over a thirty-seven year period. In that case, the Second Circuit expressed its concern that the class-member consumers may have chosen the product for a variety of reasons, such as personal preference, unrelated to the alleged misrepresentations implied in the term "light." Id. at 225-26 ("[E]ach plaintiff in this case could have elected to purchase light cigarettes for any number of reasons, including a preference for the taste and a feeling that smoking Lights was 'cool.'"). Here, however, we harbor no such concerns about intractably payor-specific issues. The evidence in the record relating to the knowledge and expectations about AWP inflation and Zoladex pricing among TPPs is voluminous, and as noted above, the portions of the

record cited by AstraZeneca as cause for concern contain strikingly consistent evidence as to each of the TPPs. We thus are not persuaded that the evidence of variation across the class members as to their knowledge and expectations about AWP inflation and Zoladex pricing demonstrates the existence of significant individualized issues in the first place, much less variations so significant as to raise concerns of a constitutional dimension.

C. Aggregate Damages

AstraZeneca's third challenge to the entry of a class-wide judgment is that the district court awarded aggregate damages "without any individualized determination of damages as to a single class member (including the named plaintiffs)," thereby violating AstraZeneca's "fundamental right" to defend against each class member's claim of injury and damages. In support of its argument that a "rough estimate" of damages is insufficient, AstraZeneca cites In re New Motor Vehicles Canadian Export Antitrust Litigation, 522 F.3d 6, 28 (1st Cir. 2008), and McLaughlin, 522 F.3d 215, for the proposition that the plaintiffs should have been required to prove that each class member was harmed by AstraZeneca's pricing practices. Requiring such proof, the company argues, ensures that AstraZeneca will pay damages reflective of its actual liability.

As to whether the plaintiffs adequately proved the class members' claims of injury, AstraZeneca once again takes aim at Dr.

Hartman's methodology, arguing that the approach he used to set the 30% liability speed limit failed to take into account the individualized circumstances of the class members. Little more need be said about Dr. Hartman's liability analysis or the district court's decision to adopt it. Suffice it to say that the methodology used to develop the 30% "speed limit" that triggered potential liability, which included an examination of TPPs' (including class representative BCBS-MA's) testimony, data, and contracts, sufficiently incorporated individualized information about the class members to support the district court's decision to adopt it for the entire class.[33]

AstraZeneca's criticisms of Dr. Hartman's damages calculation, however, merit further discussion. AstraZeneca alleges that Dr. Hartman's calculation fails to account for five factors: i) that fourteen Massachusetts TPPs and 23,000 consumers opted out of the class; ii) that those persons with flat co-payments were defined out of the class; iii) that some TPPs did not always reimburse based on AWP during the class period; iv) that some physicians did not bill patients for the co-payments; and v) that some physicians did not collect the co-payments that were billed. AstraZeneca asks us to review the district court's damages

[33]Additionally, at oral argument, plaintiffs' counsel represented to the court, without objection, that the district court will conduct further proceedings ("[t]he actual prove-up") to allow specific class members to "make their claim."

methodology for a violation of the company's due process rights, and of Federal Rule of Civil Procedure 23.

The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself. See, e.g., 3 Herbert B. Newberg & Alba Conte, Newberg on Class Actions § 10.5, at 483-86 (4th ed. 2002) ("Aggregate computation of class monetary relief is lawful and proper. Courts have not required absolute precision as to damages . . . . Challenges that such aggregate proof affects substantive law and otherwise violates the defendant's due process or jury trial rights to contest each member's claim individually, will not withstand analysis. . . . Just as an adverse decision against the class in the defendant's favor will be binding against the entire class in the aggregate without any rights of individual class members to litigate the common issues individually, so, too, an aggregate monetary liability award for the class will be binding on the defendant without offending due process." (footnotes omitted)). There is nothing about this case to suggest a contrary conclusion. Thus, to the extent that AstraZeneca argues that the district court's decision to use an aggregate damages methodology violated Rule 23 or the company's due process rights, AstraZeneca's challenge fails in the starting gate.

To the extent that AstraZeneca's arguments instead go to the question of whether Dr. Hartman's methodology was sufficiently

reliable, see Daubert, 509 U.S. at 597, we review the district court's ruling for an abuse of discretion, see Gen. Elec. Co. v. Joiner, 522 U.S. 136, 141-43 (1997), but we find none here. To begin, we note that none of AstraZeneca's first three purported errors in Dr. Hartman's damages calculations is severe enough to suggest that the district court abused its discretion in relying on it. As to the various parties who opted out of the class action, the number of opt-outs was a small fraction of the number of notices mailed: according to a signed declaration from the Notice and Administration Manager of Complete Claim Solutions, LLC, which was appointed as the Litigation Administrator below, nearly 45,000 notices were mailed to TPPs, and nearly 950,000 notices were mailed to consumers. In the scope of a gargantuan mailing effort such as this, the number of opt-outs, while large, clearly represents a very small percentage of the class. Even assuming arguendo that Dr. Hartman's analysis did indeed fail to account for parties who opted out, any imprecision that resulted was likely to be small. And if there is a more specific reason that the particular parties who opted out might have had a disproportionate effect on the damages calculation, AstraZeneca has waived that argument by failing to advance it. Zannino, 895 F.2d at 17.

Similarly, we are unable to ascertain from AstraZeneca's brief (or from the record) how Dr. Hartman's alleged failure to take into account persons who paid a flat co-payment could have

affected the reliability of his damages calculation. If AstraZeneca intends to suggest that Dr. Hartman erroneously calculated damages for these persons, who were defined out of both Class 2 and Class 3, its brief is far too opaque on the nature of the alleged error or its impact on the ultimate damages calculation for us to credit it. That argument, too, is waived. Id.

As to AstraZeneca's claim that some TPPs did not always reimburse based on AWP, the district court found to the contrary when it stated, "Throughout this period (and until today), [AWP] has also been the pricing benchmark used by most TPPS in Massachusetts and the nation." The evidence on this point may have been mixed, as AstraZeneca has argued, but not so mixed as to render either the district court's fact finding or its reliance upon Dr. Hartman's damages calculation legally infirm.

Finally, AstraZeneca's two remaining challenges -- that some physicians did not bill patients for co-payments, and that some physicians did not collect the co-payments that were billed -- are also insufficient to prove an abuse of the district court's discretion. AstraZeneca provides no argument explaining how many co-payments went unbilled or uncollected, or what impact the resulting imprecision would have on the ultimate damages calculation. Nor does AstraZeneca address the fact that the definition for Class 3 injuries includes both actual outlays of cash and legally enforceable debts, which the co-payments, even if

uncharged and uncollected, undoubtedly were. In fact, the only citation AstraZeneca offers in support of these last two challenges is to the district court's statements that doctors "could not always collect the entire co-payment from those patients who were unable to pay" and that "some doctors did not charge Medicare beneficiaries who could not afford the coinsurance payment." These statements are hardly specific enough to show that the district court abused its discretion in imposing aggregate damages. If anything, they show that the district court was mindful of potential imprecision in the aggregate damages methodology when it imposed its award, yet decided that the imprecision, if any, was negligible. But that is neither here nor there; AstraZeneca simply has not offered sufficiently developed argumentation on this point to avoid waiver. See Zannino, 895 F.2d at 17.[34]

VIII. CONCLUSION

At bottom, the district court's findings are justified. The evidence supported a finding that AstraZeneca unfairly and deceptively published an artificial average wholesale price for Zoladex that gave no indication of the actual, substantial discounts and rebates it was providing in the market. This conduct by the appellant was contrary to Congress's intent in designing the Medicare program, and it clearly transgressed the expectations of

[34]As to other arguments raised in AstraZeneca's briefs but not discussed explicitly above, we have considered them carefully and find they lack merit.

the marketplace. The scheme to maximize the divergence of the AWP from actual acquisition cost exploited consumers and the third party payors, who did not understand the systematic and extreme nature of the spreads until it was too late, and who were locked into AWP as a benchmark for reimbursement; each of these plaintiffs overpaid for Zoladex. That AstraZeneca also used the scheme to attempt to induce physicians, who stood to profit from the difference between their acquisition cost and the AWP-based reimbursement cost, to prescribe the drug to make a profit rather than based on therapeutic concerns underscores the serious nature of the company's conduct. This is precisely the kind of scheme that Chapter 93A was meant to address, and its use to impose liability here is consistent with the Constitution, with federal and state law, and with the goals, purposes, and design of the Medicare program.

We conclude that the district court made the rulings underpinning this result without committing material legal error, abusing its discretionary power, or making clear errors in its fact finding. Consequently, the rulings of the district court are **AFFIRMED.**